DELIVERABLE 9.3

30 NOVEMBER 2021

FACILITATING THE AUTHORISATION OF PREPARATION PROCESS FOR BLOOD, TISSUES AND CELLS

OPERATIONAL CONCEPT FOR AN ONLINE PLATFORM FOR PREPARATION PROCESS AUTHORISATION OF BLOOD, TISSUES AND CELLS

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Work package:	WP9 - Knowledge Sharing on Preparation Process Authorisation (PPA) between EU Competent Authorities (CA)
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Introduction

There is a wide variation in the standards of quality and safety applied to the field of blood, tissues and cells (BTC) across the EU. At the same time, there is an increasing frequency of movement of donated BTC between EU Member States (MS). In order to address the concerns regarding a lack of standardisation and to increase confidence between MS, a common approach to acknowledge authorisation of preparation processes is needed. For that purpose, it is vital to understand the basis on which BTC are regulated in MS and to share information on national preparation process authorisation (PPA) procedures.

The obvious approach to set up such an exchange of information is the development of an online platform. This document serves as a concept for such a platform. In order to prevent duplication of work that would be caused by separate platforms, we propose one single platform that allows both PPA and sharing information.

The concept was developed considering the results of other work packages (WP)[1–4] of the GAPP Joint Action and discussions with the consortium experts. The EDQM Guides[5,6] and EU directives as well as previous EU projects were taken into account. In the first step, the data from WP6, WP7, and WP8 were integrated in a single framework (see Deliverable 9.1[7]). In the second step, the framework was expanded into a framework for electronically supported PPA (see Deliverable 9.2[8]). Finally, an operational concept for a platform for PPA of BTC was created based on these two deliverables. A demonstrator as a proof of concept, was programmed and is provided as a Docker container image. The concept and demonstrator can be used in a future project to create a fully functioning platform for PPA of BTC in the EU.

Objectives

This document aims at describing a concept for an online platform for electronically supported PPA and sharing information concerning PPA procedures in MS. For the concept, Part I describes:

- the platform and its users
- the common format and template for preparation process dossier (PPD) that sets the framework for PPA of BTC and organisation of data for sharing information (presentation and content)
- application for PPA and assessment of PPA application (functions)
- safety, adaptability of the platform to meet national needs, and maintainability to ensure upkeep and improvement of the platform (performance)
- system architecture

For realization of the concept, Part II describes the design and architecture of the platform and serves as the basis for the technical conception and implementation of the platform.

Target audience

The target audience of the document geared toward platform users and developers. Although the platform requirements are defined from the perspectives of its users who will operate the platform, the document itself is created for the developers who will build out the functions. The document is interdisciplinary in approach and language.

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Part I: Platform characteristics

1 Description of the platform

The online platform supports PPA of BTC and serves for sharing information concerning PPA procedures. The PPA for BTC comprises application for PPA by blood/tissues establishment (BE/TE) and assessment of PPA application by CA. The platform allows both for initial PPA application and any subsequent submissions in the lifecycle of BTC.

From a technical point of view, it is a platform that collects, organizes and enables the export of data concerning the PPA procedures of BTC (Figure 1). The data can be collected from different sources. Some data are submitted in the application or provided during the assessment of the application, or in supporting documentation. These data include data requested for PPA (e.g. quality, safety and efficacy data) and international/national requirements and recommendations (e.g. EU directives, EDQM Guides, national legislation and guidelines). In the platform, the gathered data are organized and stored in a structured way in order to be easier to locate and to retrieve. The template for PPD, an electronic form for application for PPA developed during the course of GAPP Joint Action, was designed with particular attention to the organization of data into several categories. The structured data may then be shared among the competent authorities (CA) in the MS (hereafter referred to as national CA, referring to any concerned national or regional CA).

In future, the structured data may also be exported from the platform and analysed to contribute to data-driven decision-making. Combining the data collected from the platform with data gathered for example from the vigilance system or clinical registries may serve further possibilities for future data analysis. This remains as a topic for future projects.

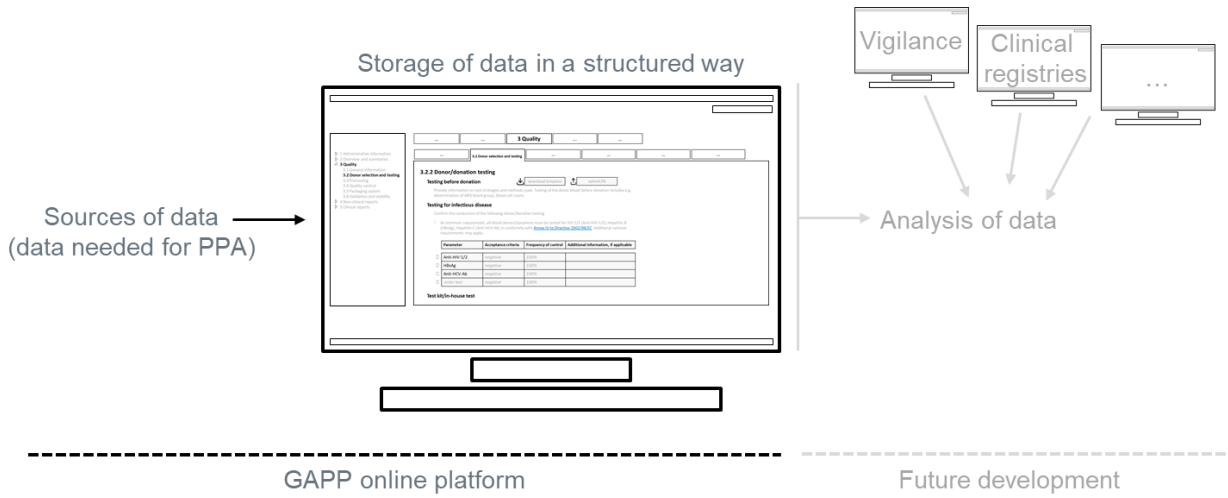

Figure 1. Online platform for preparation process authorisation and sharing of information. The data gathered from sources outside of the platform (e.g. data needed for PPA) are stored in the platform in a structured way to allow for analysis. Combining these data with data gathered from other external sources, e.g. from the vigilance system, create further possibilities for future data analysis. PPA, preparation process authorisation

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2 User classes and characteristics

Users refer to a heterogeneous group of people who operate the online platform. Users of the platform are differentiated in the context of their roles and responsibilities. The users include but may not be restricted to the following groups as illustrated in Figure 2 and characterized in Table 1: observer (anyone, EU authorities), applicant, assessor, and host. Users have access to specific functions. The functions are cumulative, meaning that applicant/assessor have access to applicant/assessor and observer functions and the host has access to host, applicant/assessor and observer functions.

Different roles and responsibilities are further associated with different levels of security in terms of data access. However, a clear differentiation must be made between the access to specific functions and data access. How data are classified in the context of security and who has a right to access which data is detailed later in Table 7 in Chapter 4.1.

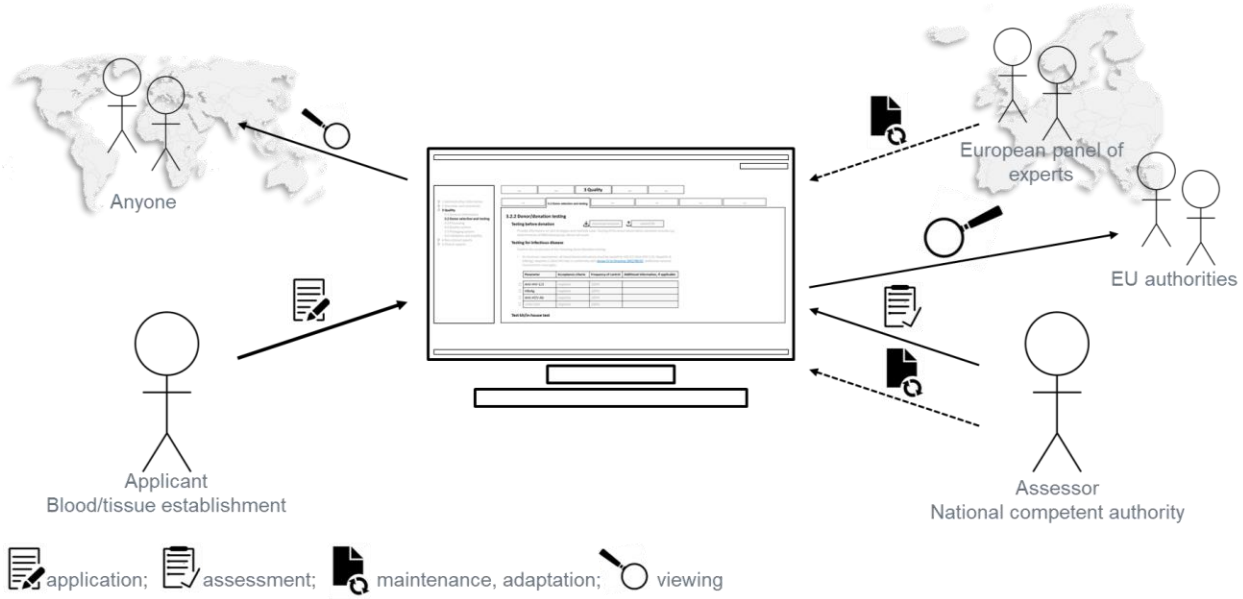

Figure 2. User classes and characteristics. Users refer to a heterogeneous group of people who operate the online platform. Users are differentiated in the context of their roles and responsibilities, which are further associated with different levels of security in terms of data access.

Table 1. User classes and characteristics.

User	Characteristics
Observer	Observer (anyone, EU authorities) refers to a person or group of people who have read-only access to the online platform with a limited access to its functionalities. Observer should be able to perform the following functions: • Viewing of the platform • Viewing of EU and national templates for PPD

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User	Characteristics
	• Viewing of data that are freely disclosed to the general public (anyone) or data that can be accessed by the EU CA and EC (EU authorities only)
Applicant	Applicant (once PPA granted, referred to as PPA holder) refers to a natural or legal person (BE/TE) who fulfils the national criteria for being eligible to apply for PPA for BTC. PPA holder is a natural or legal person who holds a PPA and is responsible for the BTC as laid down by national law. Applicant should be able to perform the following functions: • Start of application (selection of type of submission, selection of template) • Submission of application • Submission of further information (response, additional information) • Manage own applications and authorisations, manage life-cycle of own BTC
Assessor	Assessor refers to a person or group of people who fulfil the national criteria for being eligible to assess application for PPA and to make a decision on authorisation. Assessor should adapt and manage national templates for PPD. Assessor should be able to perform the following functions: • Assessment of application (initial assessment, comprehensive assessment, benefit-risk evaluation) • Decision on authorisation • Request for further information • Co-manage life-cycle of BTC • Design and adaptation of national templates for PPD (adaptation of the structure of template; translation of the adapted template; providing national forms, guidance, or other relevant documents)
Host	Host refers to a person or group of people who manage administrative functions to allow optimal and up-to-date operation of the online platform. The host should have permissions to access all functions of the platform. Host should be able to perform the following functions: • Design and maintenance of templates for PPD (adaptation of presentation and content; add and remove information requested (e.g. specifications for quality control prior to release); providing forms, guidance, or other relevant documents) • Add/delete international templates for PPD • Maintenance and adaptation of the platform

(BE/TE, blood/tissues establishment; BTC, blood, tissues and cells including medically assisted reproduction; CA, competent authority; PPA, preparation process authorisation; PPD, preparation process dossier)

3 Presentation and content

The presentation and content specify the compilation of PPD in the online platform. The common format and template for PPD indicate the organization and format for the data requested in the application and the overall framework implemented in the platform (Annex 1 and Annex 2).

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3.1 Template for preparation process dossier

Template for PPD defines the framework for an online PPA procedure (Annex 2). It is an electronic form with a predesigned, customized format and settings that serves as a basic structure for a PPA application to be filled in. Subsequent assessment of the submitted application information follows the same logical sequence as the application. The Good practice guideline[1], Technical Annexes[2–4], EDQM Guides[5,6], and EU directives set the framework for the specifications and serve as supporting documentation for PPA procedure. An overview of the development and adaptation process from the common format for PPD to a national template for PPD is shown in Figure 3.

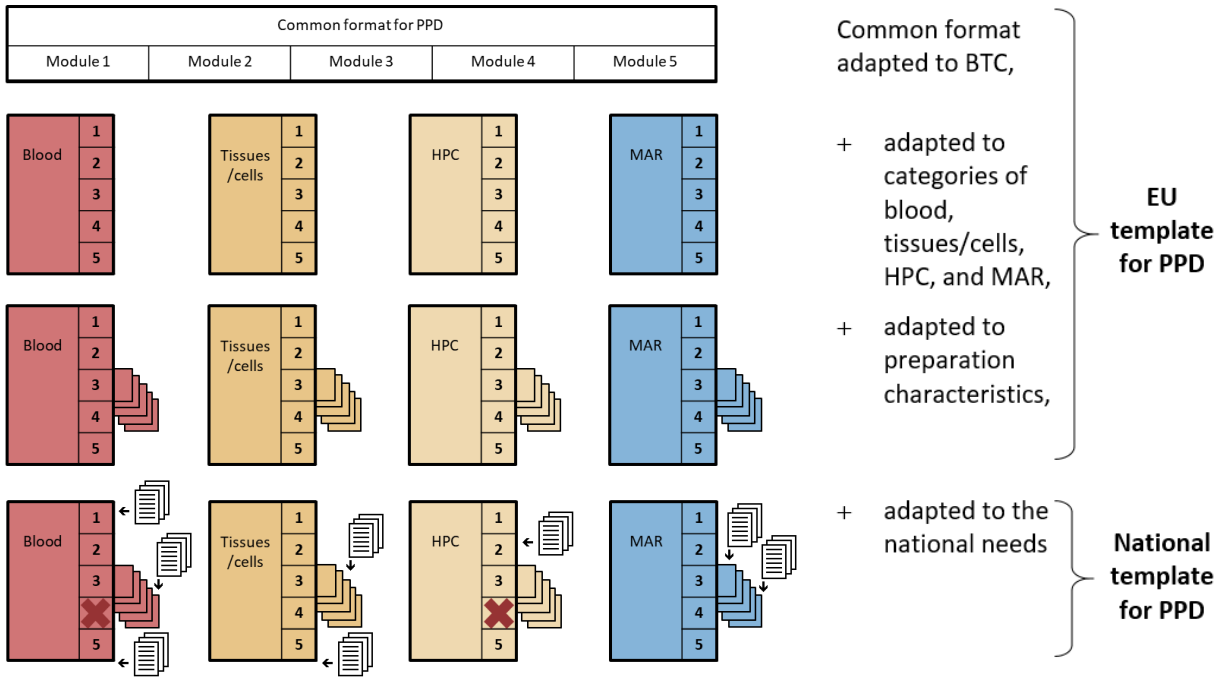

Figure 3. Template for preparation process dossier. An overview of the development and adaptation process from the common format for PPD to a national template for PPD. (BTC, blood, tissues and cells including MAR; HPC, hematopoietic progenitor cells; MAR, medically assisted reproduction; PPD, preparation process dossier)

3.1.1 EU template

The EU template for PPD was developed in three steps (Figure 3) during the course of GAPP Joint Action[7,8]. The common format for PPD is derived from the five modules of the internationally widely used and accepted Common Technical Document (CTD)[9–12] but extensively reworked to be applicable in the field of BTC. The same general structure applies across all categories of BTC (Annex 1 and Annex 3), but differences occur in terms of information requested and needed for PPA (Annex 2). These differences occur both between and within categories of BTC. Consequently, four main templates were developed, allowing differentiation of BTC. Multiple forms comprising quality control and validation specifications were created in order to cover different preparation characteristics within different categories of BTC (Annex 4). The EU template for PPD was developed both for initial as well as for any subsequent submissions in the lifecycle of BTC. Whereas the

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category of BTC determines the actual information requested in the application, the type of submission additionally determines the extent of the information requested. Further adaptation may occur at the national level.

3.1.2 National template

The platform enables the national CA to design national templates for PPD based on the EU template for PPD. The EU template can be adapted to the national needs and requirements in the following steps: adaptation of the structure of template, translation of the adapted template, and providing national forms, guidance, or other relevant documents. The sections not needed for national PPA can be removed from the structure. The actual set of information requested and its extent can be adapted. The adapted template can be translated into the national language. National guidance and other reference documents such as national requirements and recommendations, can be uploaded to provide assistance to the applicant in completing the application and to the assessor in assessing the application.

In future, in order to enhance sharing of information concerning national PPA, a minimum set of information that the applicant is requested to provide, and that also refers to the fields that cannot be removed from the template at the national level, may be defined. This set of information could correspond to the general information collected through the Tissues & Cells database[13] or EU Tissue and Cell Compendium[14].

3.2 Organization of data

Data are organized in the online platform by the common format and template for PPD. In these templates, the data submitted by the applicant are categorized into the selected category of BTC (Annex 2) as well as chronologically organized based on the type of submission (initial or subsequent submission).

3.2.1 Categorization of data

The category of BTC not only determines the actual information requested in the template for PPD (Annex 2) but also defines how the data are organized in the online platform.

For organization of data, three main categories of blood, tissues/cells, and MAR were identified. The main categories are followed by subcategories and sub-subcategories. Subcategories determine the active component and sub-subcategories the preparation characteristics. The categories are based on the categories outlined in the Technical Annex 1[2], EDQM Guides[5,6], and EU Coding Platform[15]. A comprehensive list of categories of BTC used for organization of data in the platform is provided in Annex 3.

In the platform, the main category is selected in the beginning of the application process (also later referred as a process step for selection of category). The sub-category is selected in Module 1 of the template for PPD. These categories determine the information requested in the template for PPD but also serve for categorization of data submitted by the applicant (Table 2). It is worth highlighting that hematopoietic progenitor cells (HPC), despite falling into the main category of tissues/cells in the given organization (Annex 3), is identified as a fourth category when it comes to different sets of information requested, as defined in the Technical Annex 1[2] and illustrated in Annex 2. Furthermore, MAR creates its own main category in the platform, despite the fact that reproductive cells used for MAR are regulated under TC regulation. This decision is laid down in Technical

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Annex 1[2] and justified as instead of reproductive cells and embryos, MAR procedures that can be applied cumulatively, are approved.

In the platform, the sub-subcategory is selected during the application process. This category determines the information requested in Module 3 of the template for PPD (Annex 2), in particular, information requested for quality control prior to release and for validation (Table 2). Forms with a set of quality control criteria which a novel BTC with certain preparation characteristics should conform prior to release, are provided in Annex 4.

The set of application criteria for categories, subcategories and sub-subcategories are specified in templates and forms assigned to them. Selection of category and template are equivalent in terms of meaning. Functional template selection is described in Chapter 4.1.2.

Table 2. Organization of data specified by categories of BTC. Common and specific module sections are composed to define and organize the requested data in the template for PPD.

Template for PPD	All[a]	Blood[b]	Tissues/cells[b]	HPC[b]	MAR[b]
Administrative information					
1.1 Cover letter	√				
1.2 Application form		√	√	√	√
1.3 Accompanying document and labelling	√				
1.4 Experts	√				
1.5 Vigilance	√				
1.6 Additional information	√				
Overview and summaries					
2.1 General information		√	√	√	√
2.2 Risk analysis	√				
2.3 Overview and summaries	√				
Quality					
3.1 General information		√	√	√	√
3.2 Donor selection and testing		√	√	√	√
3.3 Processing		√	√	√	√
3.4 Quality control		√ (sub-subc.)	√ (sub-subc.)	√ (sub-subc.)	√ (sub-subc.)
3.5 Packaging system	√				
3.6 Validation and stability		√ (sub-subc.)	√ (sub-subc.)	√ (sub-subc.)	√ (sub-subc.)
Non-clinical reports	√				
Clinical reports	√				

[a]Data requested are equal across all categories of BTC; [b]Data requested are special to the selected category of BTC. (BTC, blood, tissues and cells including for MAR; HPC, hematopoietic progenitor cells; MAR, medically assisted reproduction; PPD, preparation process dossier; sub-subc., sub-subcategory (sub-subcategory determining the preparation characteristics determines the information requested))

3.2.2 Chronological presentation of data

Chronological presentation of data is performed in the context of lifecycle of BTC. It defines how the data are organized in relation to the possible previous submissions over the lifecycle of BTC (Table 3). Lifecycle of BTC starts with submission of initial PPA application and may be followed by subsequent submissions (e.g. change to an existing preparation process). In the platform, each subsequent activity can be related to the previous and to the initial activity.

The data submitted in a PPD are chronologically sorted in the platform based on the type of submission and logical sequence in which the data are submitted. New data are loaded on top of the existing data and

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supplement these in the most current version of the PPD. It is possible to access past states of the PPD and to view how entries have been changed over time. The given presentation allows keeping track of all changes and activities in the lifecycle of BTC.

An illustration of how the activities relate to each other, is provided in Table 3. Applicant's selection of type of submission determines the chronological sequence and relation of the submission to the previous submissions. Determination of the chronological sequence and related sequence is programmed to occur automatically and is not visible for the applicant.

Table 3. Example of applicant's activities in the lifecycle of BTC.

Type of submission	Description of submission	Chronological sequence	Related sequence
Initial PPA application	–	1	–
↳ Further information	Response to request for information	2	1
↳ Further information	Response to further request for information	3	1
Change	–	4	–
↳ Further information	Response to request for information	5	4

(BTC; blood, tissue and cells including medically assisted reproduction)

4 Functions

The functions specify the activities and tasks the online platform should facilitate. The main function of the platform is to allow PPA of BTC. The PPA process in the platform can be broken down into four steps: start of application, submission of application, assessment of application, and decision on authorisation (Figure 4). Each of these steps is necessary for a PPA, and conducted either by applicant or assessor. Additionally, there is a possibility to request further information and respond to the request. The notification function sends a notification to the applicant or assessor whenever new information has been provided by either party in the platform.

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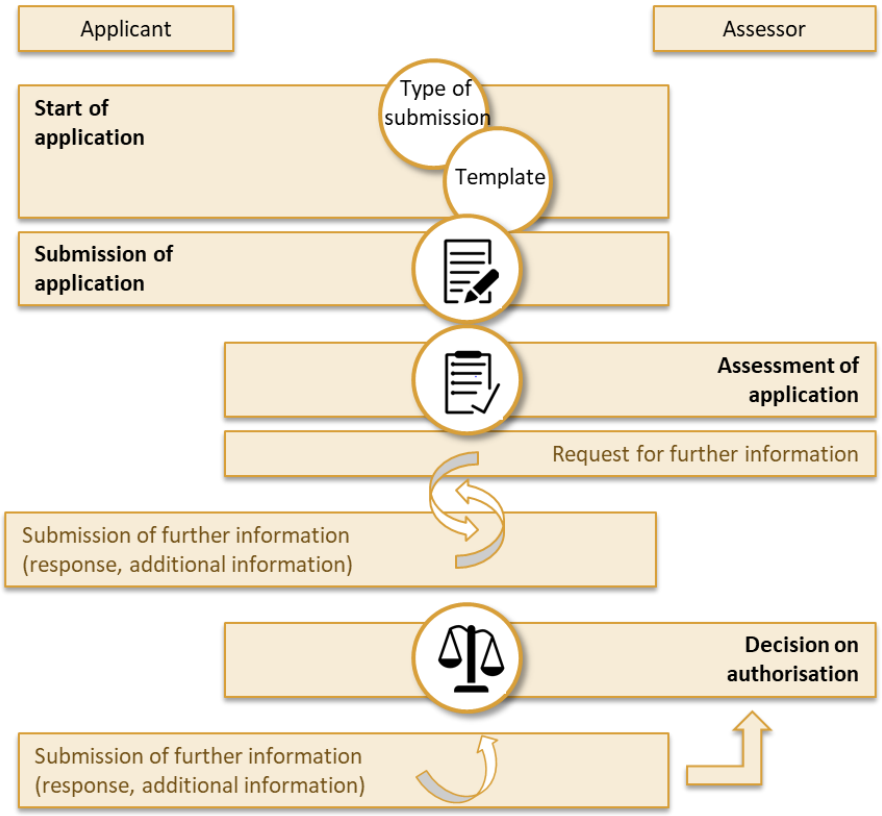

Figure 4. Steps of preparation process authorisation. Four steps conducted by applicant (left) or assessor (right) in the PPA process are illustrated. The possibility to request further information and to respond to the request is illustrated. This function is also used in order to submit information needed to convert a conditional into a full authorisation, as indicated by the arrow.

In the following sections, the PPA process steps (Figure 4) are described and the paths leading to these activities are illustrated.

4.1 Start of application

Before starting the application process, the applicant is provided with a notice about the online platform (Figure 5). This notice gives general guidance on the platform and states its applicability for PPA procedures of BTC as defined in the EU blood and tissues and cells legislation. Reference to the preliminary risk analysis is also included there (Figure 6). These descriptions are visible to the general public without logging in and appear regardless of the BTC for which PPA is intended to be applied for. Detailed guidance is provided in each section of the template for PPD and in references (including Good practice guideline[1], Technical Annexes[2–4]).

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Notice to applicant

This platform is the outcome of a European project, GAPP Joint Action. GAPP Joint Action was launched with the aim of promoting harmonisation of the authorisation of preparation processes for blood, tissues and cells including reproductive cells for medically assisted reproduction (BTC) in the EU.

This platform is developed to support the preparation process authorisation (PPA) for BTC. This comprises application for PPA by blood/tissue establishment and assessment of PPA applications by national competent authority. The platform further serves for knowledge sharing of data on PPA procedures and national/international requirements and recommendations, in accordance with the European General Data Protection Regulation and national data protection laws.

This platform is applicable to BTC and their applications, as defined in the EU blood and tissues and cells legislation. It can be applied to novel BTC, which do not fall under other regulations. The platform is not intended to be applied to advanced therapy medicinal products (ATMP) as defined in Regulation (EC) No 1394/2007 (tissue engineered products and combination products) and in Part IV of Annex I to Directive 2001/83/EC (somatic cell therapy and gene therapy medicinal products).

Figure 5. Realization of notice to applicant as shown to the applicant at the start of application.

Risk analysis

Whenever a novelty (e.g. new preparation process or a change in an existing preparation process) is introduced to BTC and intended to be transferred into clinical practice, the applicant should perform a preliminary risk analysis (EuroGTP II Guide[16]; Technical Annex 3[4]).

This risk analysis can be conducted using a risk assessment tool[17]. The risk analysis may help to determine relevant risks, risk factors, and estimate the level of risk associated with the clinical use of the BTC. Depending on the nature and level of risks, the applicant may decide to improve and validate the preparation process prior to applying for PPA authorisation or change.

Detailed information on the risk analysis is provided in Module 2 of the application.

Figure 6. Realization of description of preliminary risk analysis as shown to the applicant at the start of application.

In the next step, the applicant is guided to select the type of submission and then an appropriate template (Figure 7). These process steps are discussed in detail in the following chapters.

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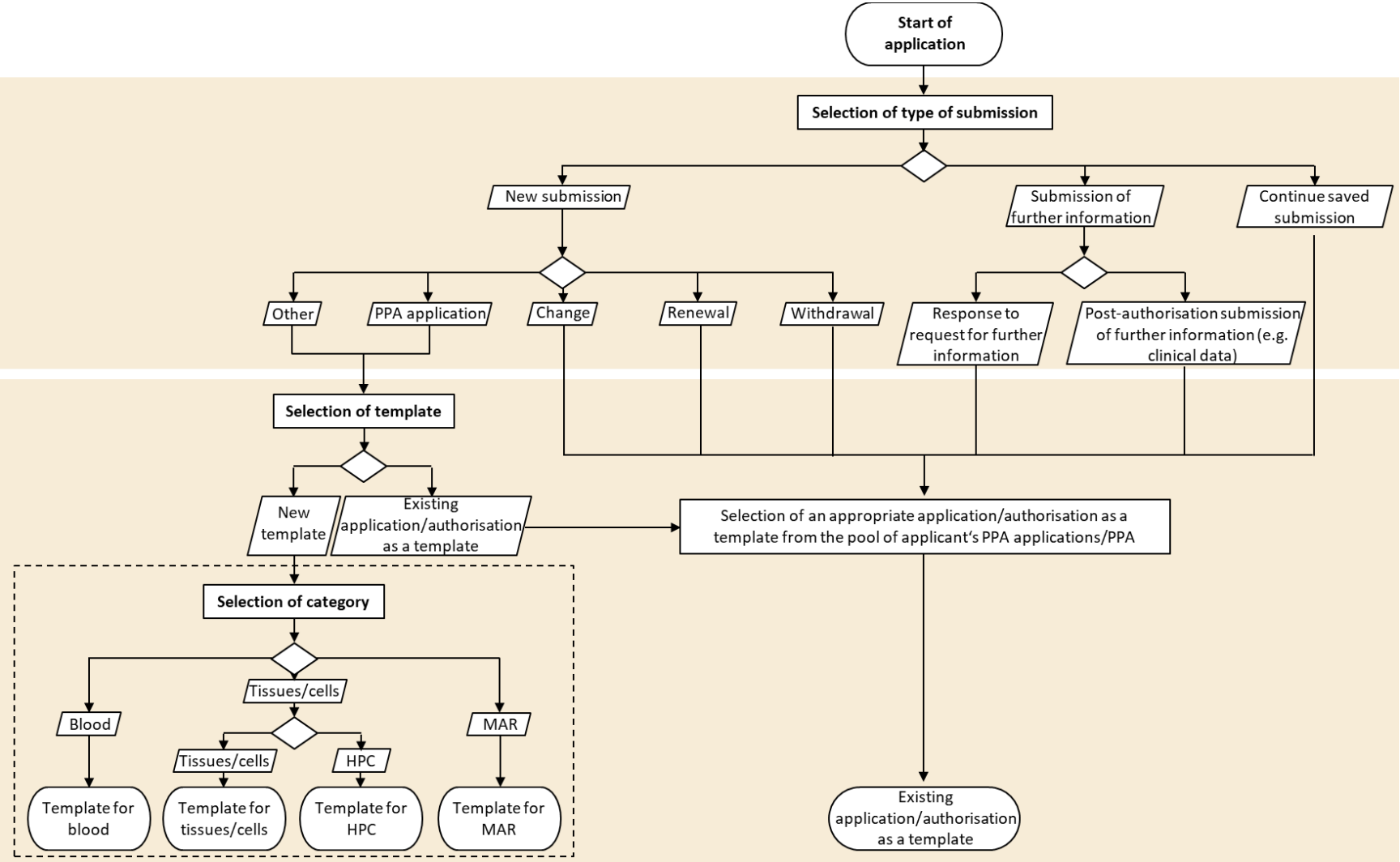

Figure 7. Selection of type of submission and template. Before starting the application process, the applicant is guided to select the type of submission and then an appropriate template, as indicated. If "new template" is selected, the applicant is guided to determine the BTC applied for. (BTC, blood, tissues and cells including MAR; HPC, hematopoietic progenitor cells; MAR, medically assisted reproduction; PPA, preparation process authorisation)

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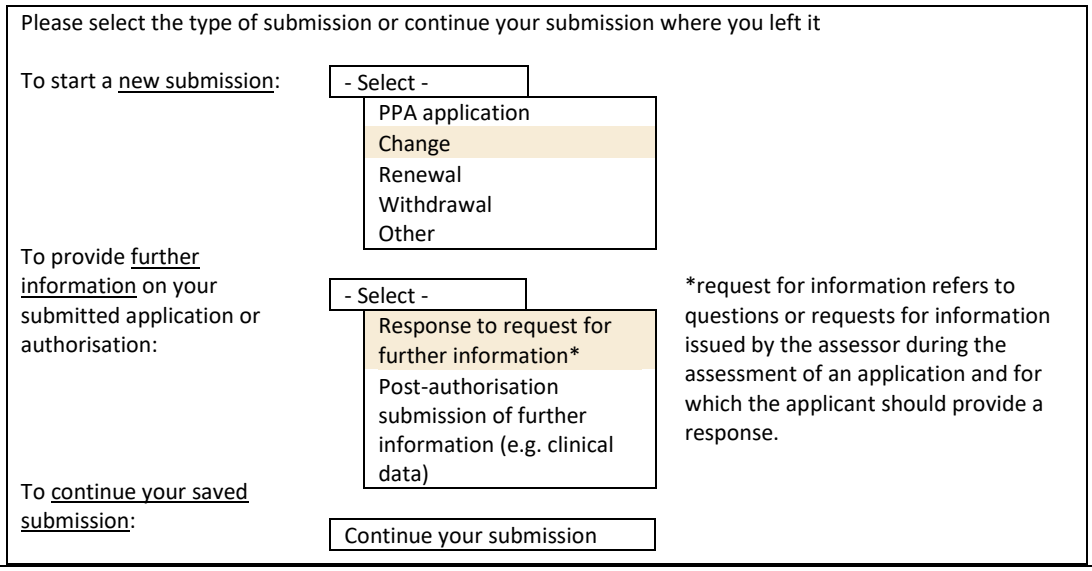
4.1.1 Selection of type of submission

The applicant is guided to start the application by selecting the type of submission (Table 4). The applicant can choose between initial PPA application, change, renewal, withdrawal, or other national type of submissions. Submission of further information is a continuation of the related activity (e.g. initial PPA application or change). Via the third button (Table 4), the applicant is taken back to the saved PPA applications, which the applicant can then continue to fill in.

Table 4. Realization of selection of type of submission.

Category	Description/instruction	Parameter	Data field type	
all	Please select the type of submission or continue your submission where you left it	N/A	N/A	(presentation is provided below)
	To start a new submission:	• PPA application • Change • Renewal • Withdrawal • Other	drop down (1)	
	To provide further information on your submitted application or authorisation: Note: *request for information refers to questions or requests for information issued by the assessor during the assessment of an application and for which the applicant should provide a response.	• Response to request for further information* • Post-authorisation submission of further information (e.g. clinical data)	drop down (1)	
	To continue your saved submission:	Continue your submission	button	



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4.1.2 Selection of template

After the selection of the type of submission (Figure 7), the applicant is guided to select a template for PPD. The templates available depend on the selected type of submission (Figure 8).

In case of initial submission in the lifecycle of BTC ("PPA application", "other"), the applicant may decide to use a "new template" or to select one of the previous applications or authorisations from the pool of applicant's PPA applications/PPA as a template for a submission (Figure 8 and Table 5). If "new template" is selected, the applicant is guided to determine the BTC to be applied for (Figure 7).

In case of subsequent submissions in the lifecycle of BTC ("change", "renewal", "withdrawal"), only already submitted applications or existing authorisations are available as illustrated in Figure 8. In that case, the applicant can select a template from the pool of applicant's PPA and PPA application. The pool consists of all applications and authorisations of a certain applicant as specified in Figure 8. Existing PPA are available as a template for post-authorisation submissions with the aim to maintain the authorisation or to incorporate any changes. A request for withdrawal can address either a submitted application or PPA and can be submitted at any stage during the evaluation process or thereafter. The given structure will support tracking of regulatory activities and the lifecycle of BTC.

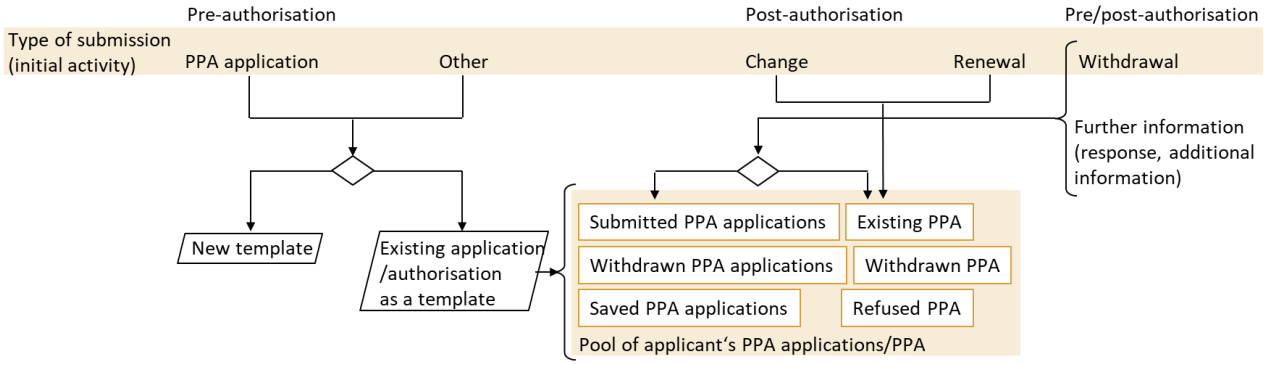

Figure 8. Selection of template in the beginning of the PPA application process. (PPA, preparation process authorisation)

Table 5. Realization of selection of template for initial submission ("PPA application", "other").

Category	Description/instruction	Parameter	Data field type	
all	Please select whether you wish to use a new template or an existing application or granted authorisation as a template for your PPA application	New template	button	(presentation is provided below)
		Existing application/authorisation as template	button	

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Category	Description/instruction	Parameter	Data field type
	Please select whether you wish to use a new template or an existing application or granted authorisation as a template for your PPA application New template Existing application/ authorisation as a template		

4.1.3 Selection of category, subcategory, and sub-subcategory

After the type of submission, the selected main category of blood, tissues/cells (including HPC), or MAR serves as a second filter function to determine further which templates can be used for the application. This function becomes relevant only for initial submissions ("PPA application", "other"), in case the applicant decides to use a "new template" (Figure 7). The information requested in the template for PPD differ by the category.

Later in the application process, the subcategory that determines the active component (e.g. ocular) and further specification (e.g. corneal) can be provided. In Module 3, an appropriate or most suitable form is selected for quality control prior to release and validation for a particular sub-subcategory that determines the preparation characteristics.

In Figure 9, the described selection process is illustrated for four theoretical cases (see paths 1–4). The applicant might follow the selection path and find the appropriate form for the applied BTC. If no appropriate form is available, the applicant might select "other" to use a related already existing form or an empty form without pre-filled values. Related form refers to e.g. a form for sclera used for cornea (see path 2 illustrated and described in Figure 9) or a plasma form used for COVID-19 convalescent plasma. The possibility to track the selection path creates valuable information that is required for possible future updates of templates and forms. For instance, in case an appropriate form is not available for a particular BTC and a form intended for another BTC is frequently used, the platform may be updated accordingly.

The assessor might want to track the template and form selection process of the applicant since the pre-filled values as well as the pre-provided acceptance criteria (e.g. for quality specifications) are accurate when a particular form used is fully applicable (see path 1 illustrated and described in Figure 9**Fehler! Verweisquelle konnte nicht gefunden werden.**). In case a particular form is used for application for another BTC than primarily intended for (see paths 2, 3 and 4 illustrated and described in Figure 9), additional attention may be needed when assessing the application because the pre-filled values might be misleading.

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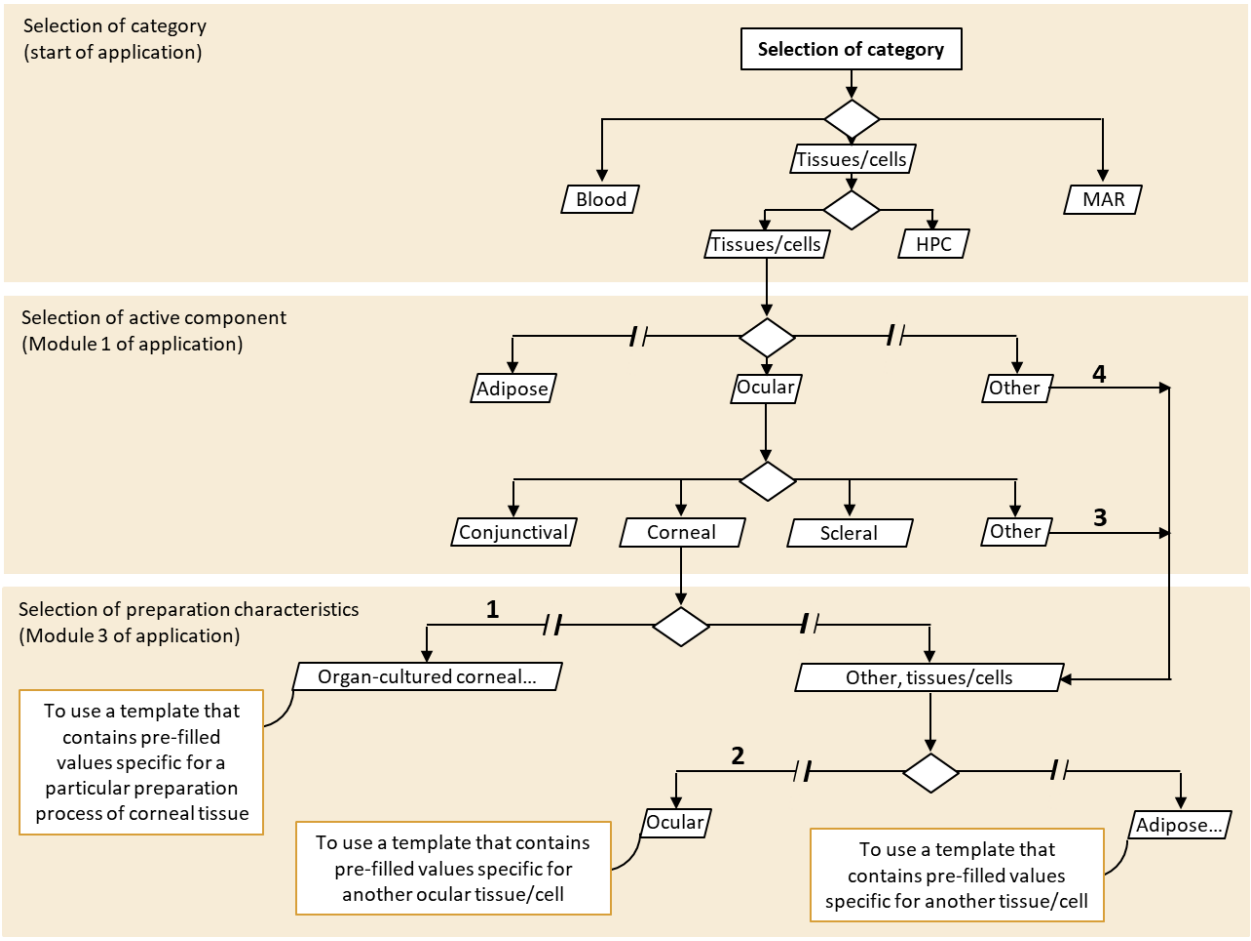

	Selection of category and active component	Selection of preparation characteristics			Clarification
1	ocular, corneal	e.g. organ-cultured corneal…			well-known ocular tissue, well-known PP (appropriate template is selected)
2	ocular, corneal	other, tissues/cells	ocular, e.g. scleral	e.g. scleral form	well-known ocular tissue, novel PP (most suitable template is selected)
3	ocular, other		ocular, e.g. corneal	e.g. organ-cultured corneal…	'novel' ocular tissue, novel PP (most suitable template is selected)
4	other		ocular, e.g. corneal	e.g. organ-cultured corneal…	'novel' tissue/cell, novel PP (most suitable template is selected)

Figure 9. Example selection of template for PPD by the start of application and in Module 3. Four theoretical options are illustrated and described. (HPC, hematopoietic progenitor cells; MAR, medically assisted reproduction; PP, preparation process)

4.2 Submission of application

The applicant fills in the template for PPD composed of a series of fields disclosing information needed for PPA. Only fields relevant to a certain type of submission and category of BTC, as selected in the previous step (Chapter 4.1), are displayed. In case of initial submission ("PPA application"), all relevant information should be provided, whereas, in case of subsequent submission ("change", "renewal", "withdrawal"), only information considering the change applied for, should be revised. There is no need to include all documents requested for an initial submission in subsequent submissions. The set of information requested further depends on the

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category of BTC. Further differences in terms of fields displayed may occur depending on settings done based on information needed for PPA at the national level.

However, even if a field is displayed, there is no obligation to fill in every blank in order to be able to proceed with the application. If some information requested in the template for PPD is considered irrelevant by the applicant, the applicant may decide to leave the sections in question blank. The system would even allow submitting a blank application. However, since registration and identification of the applicant, BE/TE, before submission is obligatory, no blank submissions are expected.

Guidance on the technical aspects can be found in each section of the template for PPD in the platform. In the template for PPD, fields relevant for a certain application only appear after ticking the appropriate box. Some fields are filled in by choosing a value from a drop-down list and some fields by selecting single or multiple values by checking the appropriate checkboxes. Depending on the requested information either one or multiple choices or entries are possible. Where necessary, the applicant can add a row in a table or duplicate the fields by clicking the [+] symbol.

Once the applicant has completed the application, the applicant submits it for the assessment. The applicant must ensure that the application meets the relevant regulatory requirements for content.

4.3 Assessment of application

Once the application has been submitted, the assessment is conducted in the steps of initial assessment, comprehensive assessment, and benefit-risk evaluation, and finally leads to decision on authorisation (Figure 10). The necessary assessment steps can vary depending on the type of submission (“PPA application”, “change”, “renewal”, “withdrawal”) to which the content is submitted. National differences may occur.

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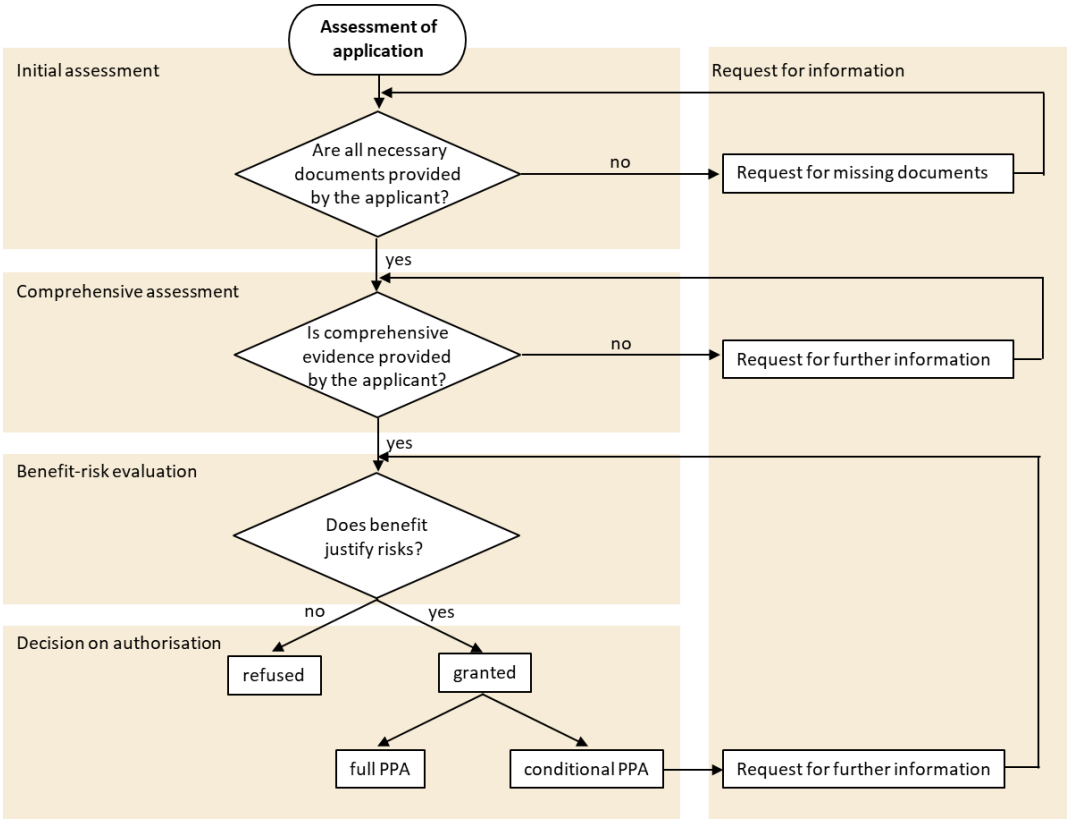

Figure 10. Assessment of application leading to decision on authorisation in the online platform. (PPA, preparation process authorisation)

Request for further information and response to the request, which can take place at any stage of the assessment process, is described below in Chapter 4.5.

4.3.1 Initial assessment

In the conduct of initial assessment, the assessor examines if the application documents are formally complete. Depending on whether all necessary documents have been included in the PPD or not, the assessor considers the application either accepted or not accepted for evaluation. In case the application is considered "not accepted" for evaluation, the assessor can inform the applicant and request for missing documents via the platform.

4.3.2 Comprehensive assessment

In the conduct of comprehensive assessment, the assessor assesses the evidence provided on BTC. Different sections of application can be appointed to different experts (e.g. risk management plan, quality data, pre-clinical data, clinical data). The appointed experts can conduct their assessments of distinct sections of the application at the same time.

There are different features to support the assessment of application and evaluation of the information submitted (Table 6). Some of them are visible for the applicant when viewing is allowed, while others allow only for assessor's own notes.

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Table 6. Features to help comprehensive assessment.

Features visible for assessor and applicant when viewing is allowed		
✔ / ✘	accept/decline	The assessor can either accept or decline a specific entry. Alternatively, the assessor can request further information associated with a particular entry. In case a prefilled value is provided for the applicant (e.g. specifications for quality control prior to release), this value also serves to indicate whether the value submitted by the applicant falls within the scope of preprovided value. This function provides assistance for the assessor only if an appropriate form considering the preparation characteristics has been selected by the applicant. Regardless of the form, the decision whether to accept or decline a value, is always made by the assessor. Via the comment feature, the assessor may decide to add a comment to provide reasoning for the decision. "Accept" and "decline" statements cannot be selected simultaneously.
?	Request for further information	Any issues, concerns or questions needed to be addressed by the applicant, can be highlighted. The assessment of application may consist of few rounds of requests for further information and responses.
	GDPR violation	Personal donor and patient data that would be classified as restricted (Chapter 5.1) and protected by the GDPR, are not allowed to be saved in the platform. CA can tag and request removal of any restricted information submitted by the applicant.
Features visible only for assessor		
△	Potential/identified risk	Any potential/identified risk detected during the assessment of application can be highlighted. This function and possibility to list up all the potential/identified risks will facilitate the benefit-risk evaluation (Chapter 4.3.3.
	Assessor's notes	The assessor can take notes while assessing the application. The notes are associated with the section in which they are taken.

In the end, the assessor has the possibility to view and go through the evaluation in form of a list (Figure 11). The assessor may want to select all "accepted" or "declined" values or to create a list of all issues marked with "request for further information". The selected values will appear in a list but always be linked to the sections of the application in which they are selected. The list of selected values can be forwarded to the applicant.

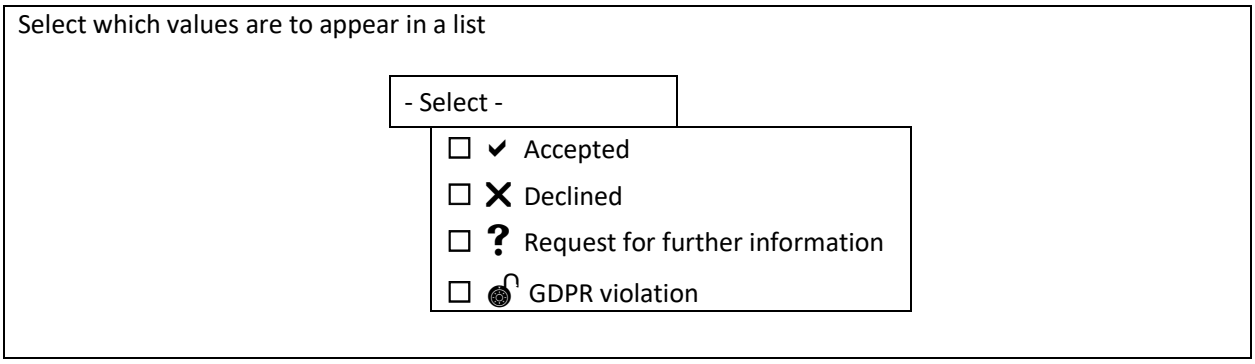

Figure 11. Realization of feature to allow listing of assessed values following comprehensive assessment.

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4.3.3 Benefit-risk evaluation

For the benefit-risk evaluation, the benefits of BTC are balanced against the risks in a distinct section of the platform. In this section, the assessor can list the benefits and the risks including any uncertainties or limitations in a tabular format. The potential/identified risks detected and tagged during the assessment of application (Table 6) may serve as a starting point for the risks evaluation. The risks taken into account in the final benefit-risk evaluation include but are not limited to the risks determined by the applicant in the preliminary risk analysis. Finally, the benefit-risk balance is evaluated.

4.4 Decision on authorisation

Decision on authorisation is based on the benefit-risk balance. It is issued by the national CA in the light of the data available and according to the national regulation and practice. Via the platform, the CA can either grant or refuse an authorisation. If all necessary data are available at the time of application and the benefits outweigh the risks, the full authorisation of preparation process is recommended. In case the data available are not as extensive as needed for the full authorisation, the conditional authorisation may be granted if the benefits of having the BTC fast available to patients outweigh the risks of having a less comprehensive set of data available. As a condition, the BE/TE may be requested to provide, for instance, the results of clinical follow-up and/or further clinical investigation (Technical Annex 3[4]) within a defined period of time or a defined number of treatments. The BTC granted the conditional authorisation may go on to receive the full authorisation after the data requested as a condition to the full authorisation, are collected and provided to confirm the positive benefit-risk balance. National differences in types of authorisations may occur, and the flexibility in that sense is provided. An assessment report can be uploaded, and a copy of authorisation certificate or other relevant documents can be provided. The applicant can be informed about the decision on authorisation via the platform.

4.5 Request for information

Request for information and response to the request are possible in the platform during the assessment process. Post-authorisation data, e.g. clinical follow-up data provided with the aim of converting a conditional into a full authorisation, can also be submitted through this function.

During the assessment, the assessor can highlight any issues, concerns or questions needed to be addressed by the applicant. The requests may be addressed by the applicant by answering a question by providing a free text description, with or without changes in the actual content of the PPD. All changes made in the content are clearly indicated, in order to allow the assessor easily to spot and review them. The changes made in the content are automatically historicised. The change history can be traced and prior entries viewed (see Chapter 3.2.2).

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5 Performance

The performance specifies quality attributes, which set out how the online platform should perform. These are essential to ensure usability and effectiveness of the platform in order to ensure good user experience and ease of operating the platform. The main quality attributes affecting the performance include security, adaptability, and maintainability.

5.1 Security

Security refers to the ability to maintain the confidentiality and integrity of the online platform and hence to assure that all data stored in the platform are protected from unauthorised access. The security qualities are related to data ownership, access and classification. How data security is ensured and translated into concrete functions in the platform is discussed later in the IT security and data privacy concept (Chapter 12).

The data stored in the platform cover data requested for PPA. These may include patient-level data collected in clinical follow-up/investigation or via vigilance. Patient-level data are allowed to be stored in the platform, however, only if these are processed in such a way that no data can be attributed to an identifiable person.

The data requested for national PPA as well as assessment-related data are stored at the national level. Consent from the MS is needed before any data may be shared among other MS CA. Although data sharing is coordinated and supported at the EU level, the responsibility of checking and protecting the data always remain at the national level.

Classification of data is performed in the context of data security. Data with similar level of sensitivity and impact in case the confidentiality, integrity or availability of the data is compromised, are grouped into the same data classification. Following data classifications are proposed as defined in Table 7: public, EU CA-only, national CA-only, and restricted. Although not all proposed data classifications are defined yet in terms of the actual data grouped into a particular classification, these classifications are considered relevant and should be subject of future work.

Table 7. Classification of data.

Classification	Definition
Public	Public data refer to data that can be freely disclosed to the general public and are available to anyone. These data require no confidentiality. Data classified as public in the online platform may cover the same data as shared by the EU Tissue and Cell Compendium[14], in the EU Tissue and Tissues & Cells database[13], or possible other platforms, and agreed among MS.
EU CA-only	EU CA-only data refer to data that can only be accessed by the EU CA and EC. These data refer to a more comprehensive set of data than that disclosed to the general public. These data serve for sharing of information.
National CA-only	National CA-only data refer to all data that can only be accessed by a designated national CA. These data refer to all data from national application and assessments.

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Classification	Definition
Restricted	Restricted data refer to any confidential or sensitive data (e.g. personal data) that is protected by the law. In the EU, the General Data Protection Regulation (GDPR) applies. Some data that would be classified as restricted, such as personal donor and patient data, are not allowed to be saved in the platform. CA can tag and request removal of any restrictive information submitted by the applicant (Chapter 4.3.2).

(CA, competent authority; MS, Member States)

5.2 Adaptability

Adaptability speaks up to national CA and their possibilities to adapt the PPA process to meet national needs, requirements and recommendations. While the functions (application and assessment processes) of the platform remain the same, the platform is to provision for changes in the presentation and content. In particular, the platform is required to be flexible enough to allow adaptation of the structure of template, translation of the adapted template, and providing national templates, guidance, or other relevant documents, as discussed in Chapter 3.1.2. Adaptability reduces the likelihood that the platform becomes obsolete at the national level.

In particular, the platform is adapted at the national level in order:

- to be usable at the national level
- to maximize efficient use of the platform

National CA are in charge of adaptation.

5.3 Maintainability

Maintainability refers to the possibilities to maintain the platform over time. Given the current discussions on revision of the EU legislation of BTC, implementation of future changes will be needed. The maintainability involves continuous upkeep and improvement of the platform.

In particular, the platform is maintained at the EU level in order:

- to cope with a changing regulatory environment, and scientific and technological capacities in BTC
- to maximize efficient, reliable and secure use of the platform
- to extend the life of the platform

An EU panel of experts, if set up in the future, is proposed to become in charge of the maintainability activities of the platform at the EU level. MS are in charge of the maintainability of national servers.

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6 System architecture

The online platform must not only be established, but also continuously adapted to changing requirements and kept up-to-date. In order to handle this, the flexibility concept (EC master templates that can be highly flexibly adapted to national requirements by national CAs) demands a solution on two levels - the EC level and the national level (Figure 12).

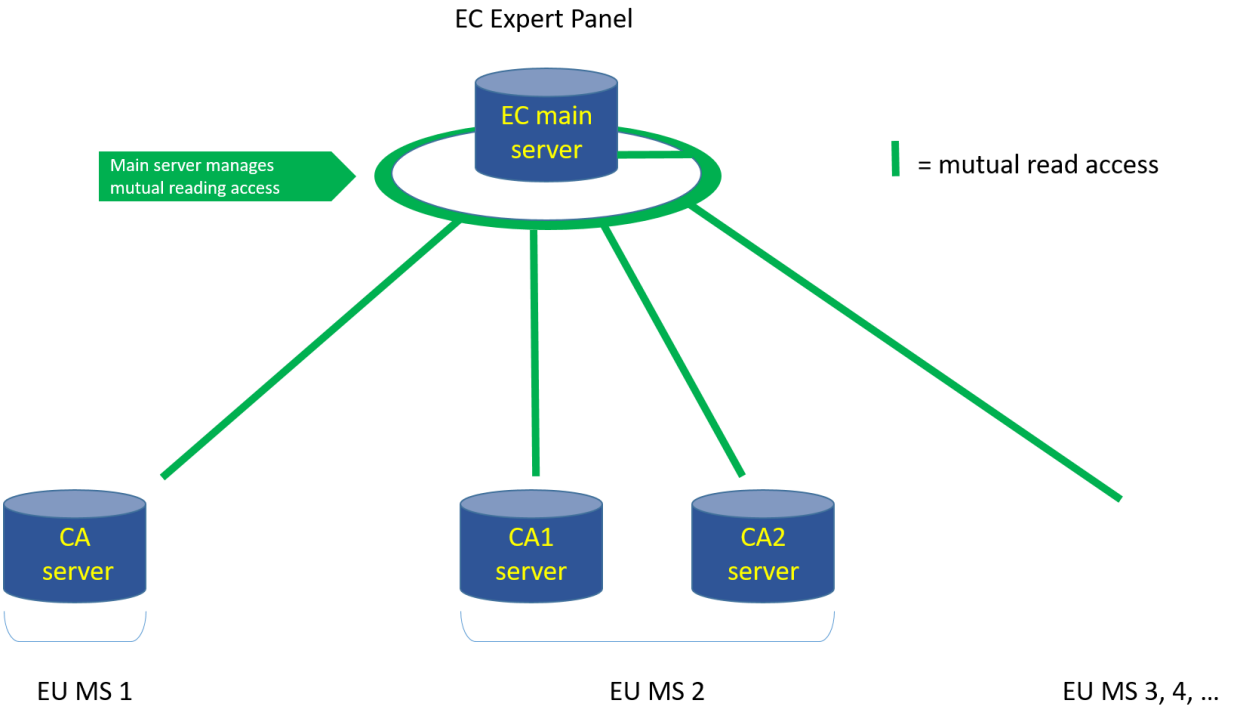

Figure 12. The different tasks of the EC and the CA are best performed in a decentralized manner. Due to the superordinate task on the international level (international master templates, requirements and information) and the subordinate one on the national level (national adaptation and translation), a system on two levels is appropriate: EU level with EC main server and MS level with its CA servers. Only read access is granted to each other but no write access.

The EC level provides on an EC main server the international master templates for application and assessment, which contain the PPD structure, the structures adapted to the categories (B, T/C, HPC, MAR) and the international templates for the sub- and, if applicable, sub-subcategories. It provides maintenance (adjustments, updates, corrections, etc.) and further development on a

- technical (software fixes and adaptations, e.g. functions, layout, etc.),
- regulatory (e.g. transfer of requirements from new directives, which may affect the PPD structure) and
- functional (e.g. changes of prefilled values in templates after revision of the EDQM guides) level.

The proposed EU panel of experts with experts from the areas of BTC, regulation and IT could be responsible for the platform maintenance on the EU level. In a further step later to be developed, the EU panel of experts

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should also be responsible for carefully analyzing the resulting comprehensive database. Data professionals will also be needed in the EU panel of experts' team to develop and apply the appropriate analytical tools. If measures are considered to promote EU-wide harmonisation of BTC authorisation, these could be communicated by the EU panel of experts to the CA of all MS via the platform. However, this should not be solved via a write access on the CA servers, but via automatic and mandatory updates that the CA servers obtain from the EU main server (see mutual read access in Figure 12). This avoids the servers having to obtain write access to other servers.

At the national level (one server for each MS or for each CA in a MS), the international master templates are first adapted to national requirements. After that, technical, regulatory and functional maintenance is also required. For example, new or updated national requirements, immediate regulatory reactions to national crisis situations or corrections must be transferred to the platform. If necessary, the settings and functions for knowledge sharing must be adapted. The competence here lies with the CA.

This two-level concept fulfills several requirements, most of which defined in the course of the GAPP Joint Action, e.g.:

- Data for national authorisations are thus stored in the respective MS and are under full control of the MS.
- National access for maintenance purposes and for updating national requirements and templates is facilitated.
- Stricter national data protection requirements can be implemented.
- If the EU main server or a national server is attacked, the (other) national servers are independent and have a better chance to continue working.

It should be noted that mutual read access is organized and managed by the central EU main server (see Figure 12). Thus, there is no read access between the CA servers directly, but only via the EU main server. The central EU server checks the access right of the requesting servers and forwards requests only if the requestor can prove his authorisation. This serves on the one hand to protect the entire network and on the other hand to promote an open and fair exchange of data and information. Excluded from this exchange is, of course, all data that cannot be exchanged between the EU CA according to Table 7.

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Part II: Design and development process

The specialist concept (Part I), the technical concept (Part II) and the demonstrator could only be developed in parallel for organizational reasons. Therefore, not all specifications from the specialist concept could be represented with the demonstrator. However, the demonstrator highlights the important aspects, so that one can get an idea of how the online platform may finally look like after implementation. The appearance of the assessment area, as the most important building block for the GAPP Joint Action - the assessor interface - identically reflects the requirements of the specialist concept.

7 Relevant actors

Relevant user roles with authorisation are

- **Applicant**: Employees of the preparation unit
- **Assessor**: Employees of authority unit (e.g. national CA)
- **Observer:** Member of observer Unit (e.g. European Commission)

There will also be users with **public access** with a restricted range of functions (Figure 12 and Table 8).

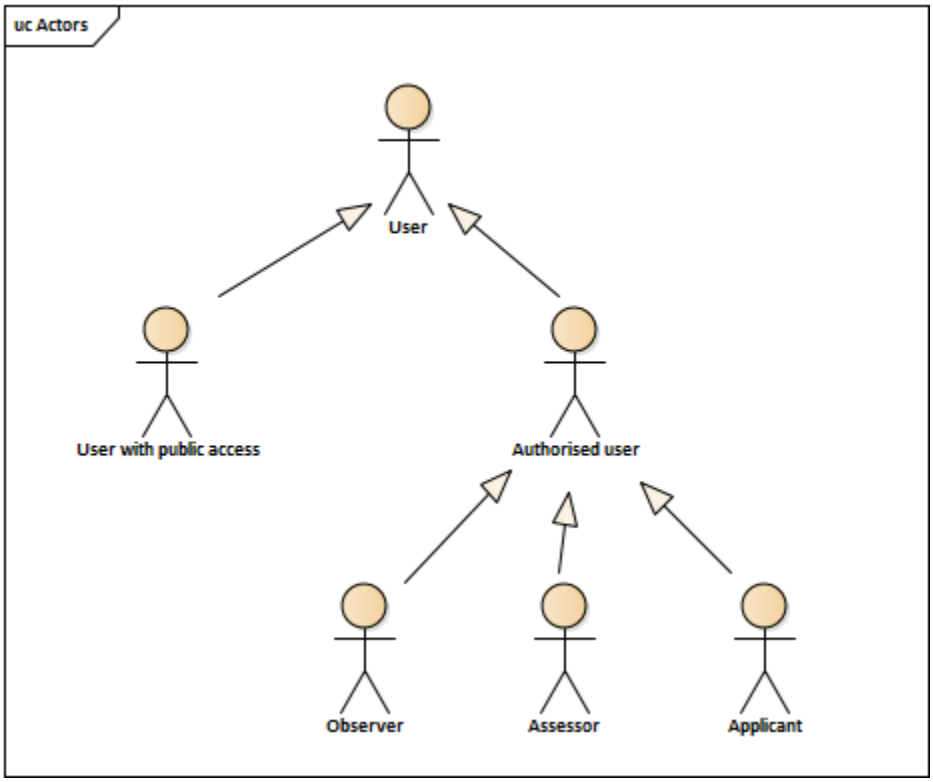

Figure 13. Actors.

Table 8. Use Role Permission Matrix

	User with public access	Applicant	Assessor	Observer

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view current assessments		x	x	x
view previous assessments		x	x	x
start new application		x		
review application			if responsible	
edit application		if own application		
view requirements /forms (authorisation parameter based on guidelines)	x	x	x	x
upload new requirements (authorisation parameter based on guidelines)			x	

8 Lifecycle of an authorisation

The lifecycle of authorisation describes the statuses of an assessment through the whole authorisation process. Assessments contain data that is needed to go through the different stages to the admission of a product. This data includes administrative information, a set of authorisation parameters, entered values, notes, additional documents and a history of previously entered values. In the process of authorisation, the assessment goes through the states shown in Figure 13. Assessments are always in one of the following states.

- **Initialized**: The applicant starts the process of authorisation to apply for approval of a product. Reasons for an application can be a new product, changes in product or regulatory changes. An application form is automatically generated according to the product type and country of admission.
- **In Progress**: The applicant can edit the application. He fills the form with administrative information and details about the preparation process. He can upload documents and leave comment or explanations. If the authorisation unit has already reviewed the application, only rejected parameters need to be entered. The applicant then releases the form for examination by the authorisation unit.
- **Under examination:** a member of the authorisation unit reviews the application. It can then be rejected or approved. If the application is rejected it returns to the status “in progress” and can be edited by the applicant.
- **Approved:** The application is accepted and the preparation process authorisation is granted. This status is valid until the preparation process changes or other reasons for a new application occur. If the need for a new application is caused by regulatory changes, a time limit is set, in which the applicant needs to start a new application process.
- **Canceled:** The assessor or applicant has canceled the assessment. The admission is no longer valid. To approve the product or preparation process the applicant needs to start a new assessment.

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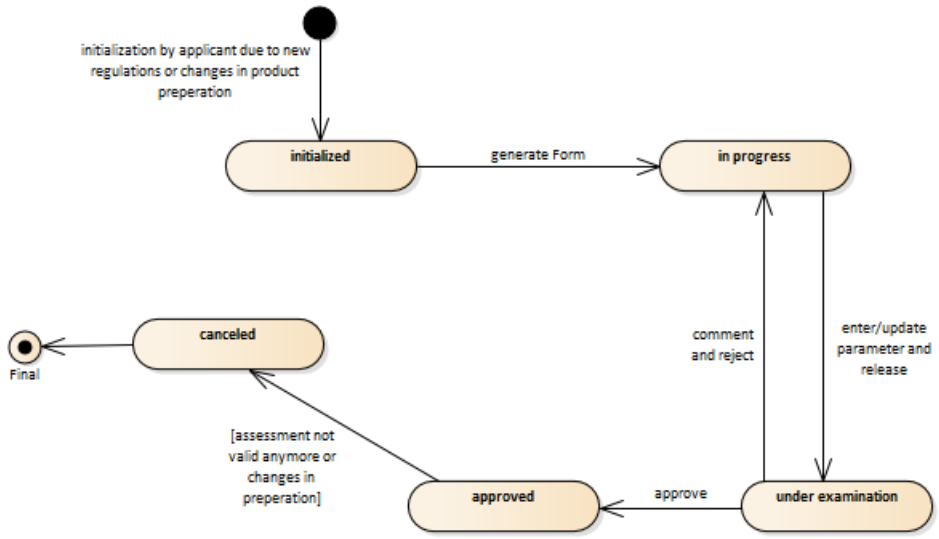

Figure 14. Lifecycle of authorisation.

9 Components of the platform

Figure 14 outlines the architecture of the online platform.

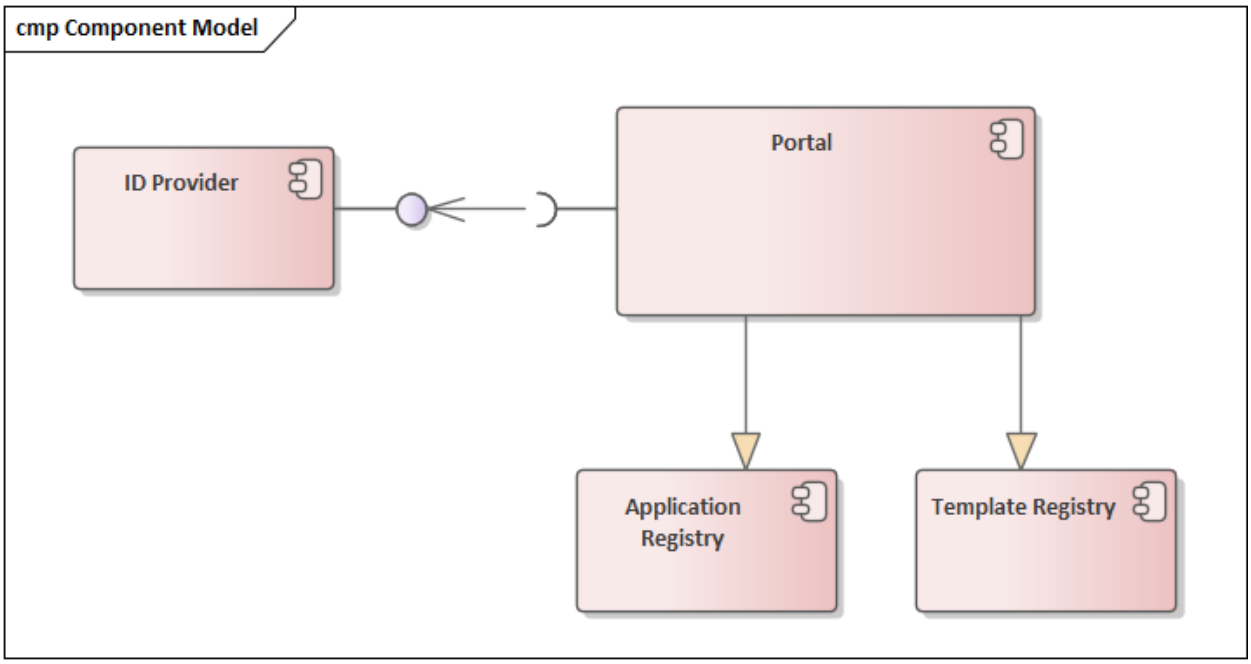

Figure 15. Architecture of the online platform.

The role of the components of the architecture is described in Table 9.

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Table 9. The role of the components of the architecture.

Component	Description
ID Provider	The ID provider is used to authenticate users and issues a trusted identity token, which is used for further transactions.
Application Registry	This component serves for overall application management and comprises all parameter relevant for the authorisation based on templates of relevant regulations
Template Registry	This component serves for template management and comprises all authorisation parameter of different regulations and supports the update of templates.
Portal	This component represents the user interface.

10 Transaction diagrams

Authentication

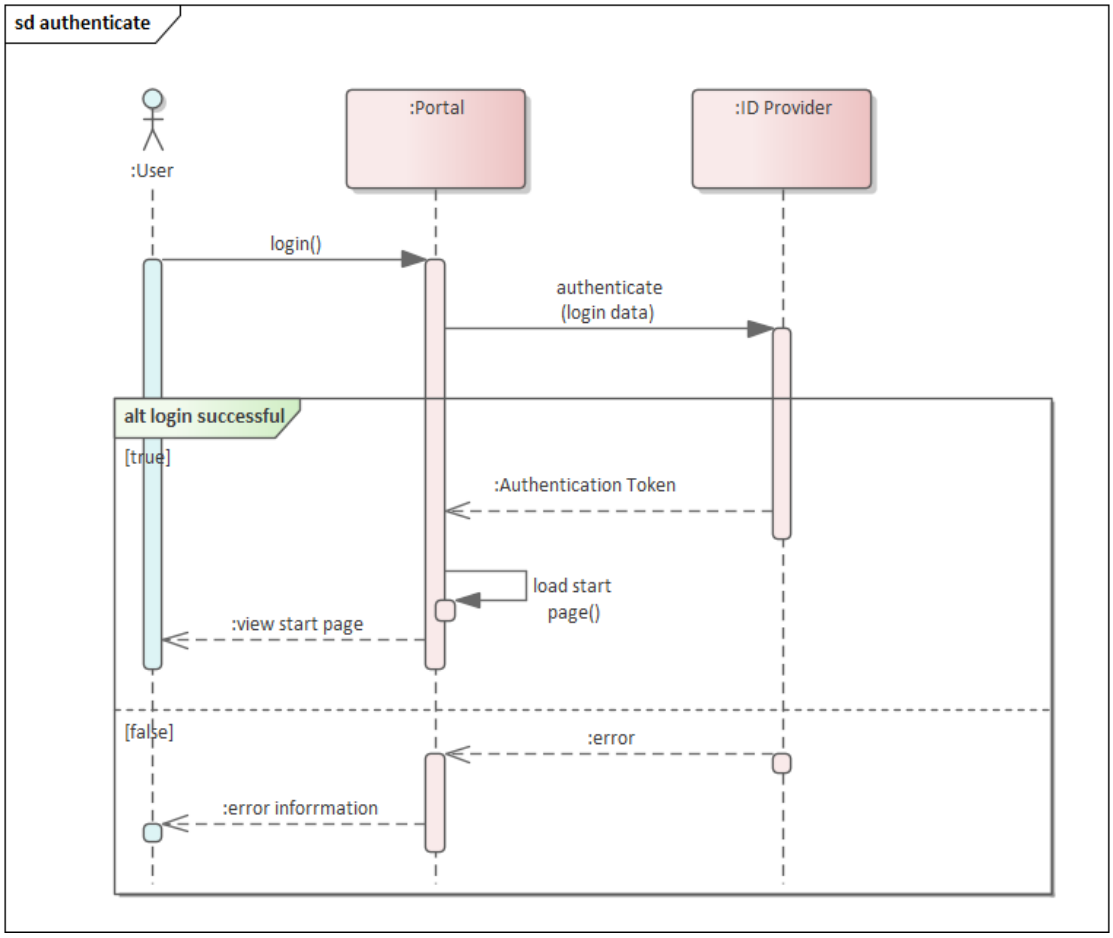

Figure 16. Sequence diagram authenticate.

Aspect	Description
Use case Name	Authentication

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Use case id	1
Description	The user authenticates himself with his access data at the online platform
(Super use case)	-
Preconditions	• actor is registered in the online platform
Use case steps	1. The actor enters his access data in the LOGIN window. 2. The actor confirms the entry by activating the "Login" button. 3. An authentication request is sent from the portal to the ID provider. The ID provider checks if the actor is registered. 4. The actor is authenticated with his data. 5. The portal receives an identity assertion, which is sent along for further identification and authorisation verification transactions.
Expected result	• The actor is authenticated • The actor is forwarded to the start page

View applications

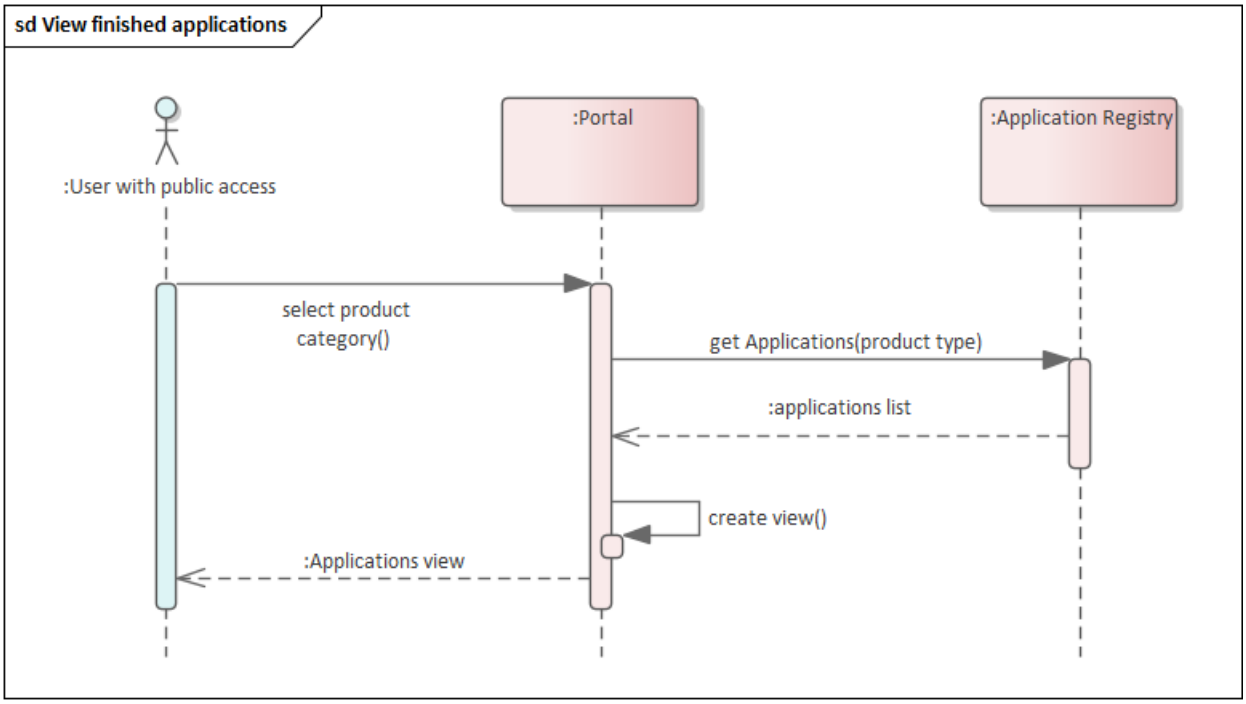

Figure 17. Sequence diagram view applications

Aspect	Description
Use case Name	View applications
Use case id	2
Description	The authenticated user displays all applications to which he has access to.
(Super use case)	-
Preconditions	• User is authorized to view applications
Use case steps	1. User selects “view applications”

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	2. User is redirected to the application page 3. System shows list of applications which can be sorted and filtered
Expected result	• List of applications which can be sorted and filtered.

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Initiate new application

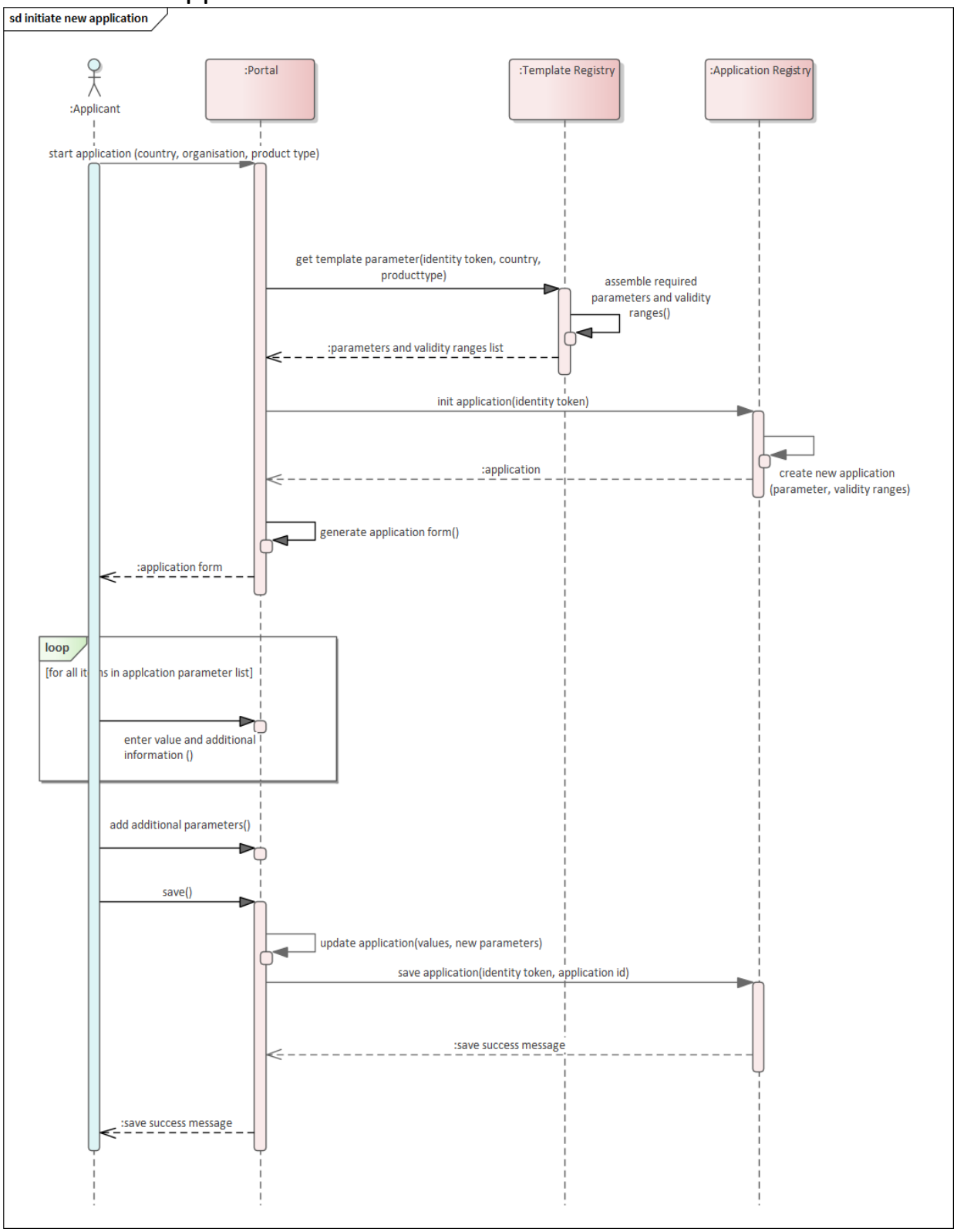

Figure 18. Sequence diagram initiate new application

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Aspect	Description
Use case Name	Initiate new application
Use case id	3
Description	The user creates a new application based on a template.
(Super use case)	-
Preconditions	• User is authenticated as applicant
Use case steps	1. User enters application page 2. User selects “new application” 3. User search a template for application. 4. System generates form according to template 5. User enters all values in form and adds additional information 6. User adds additional parameters (optional) 7. User selects “release” 8. System saves application and returns save message
Expected result	• New application is created

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Initiate application from existing

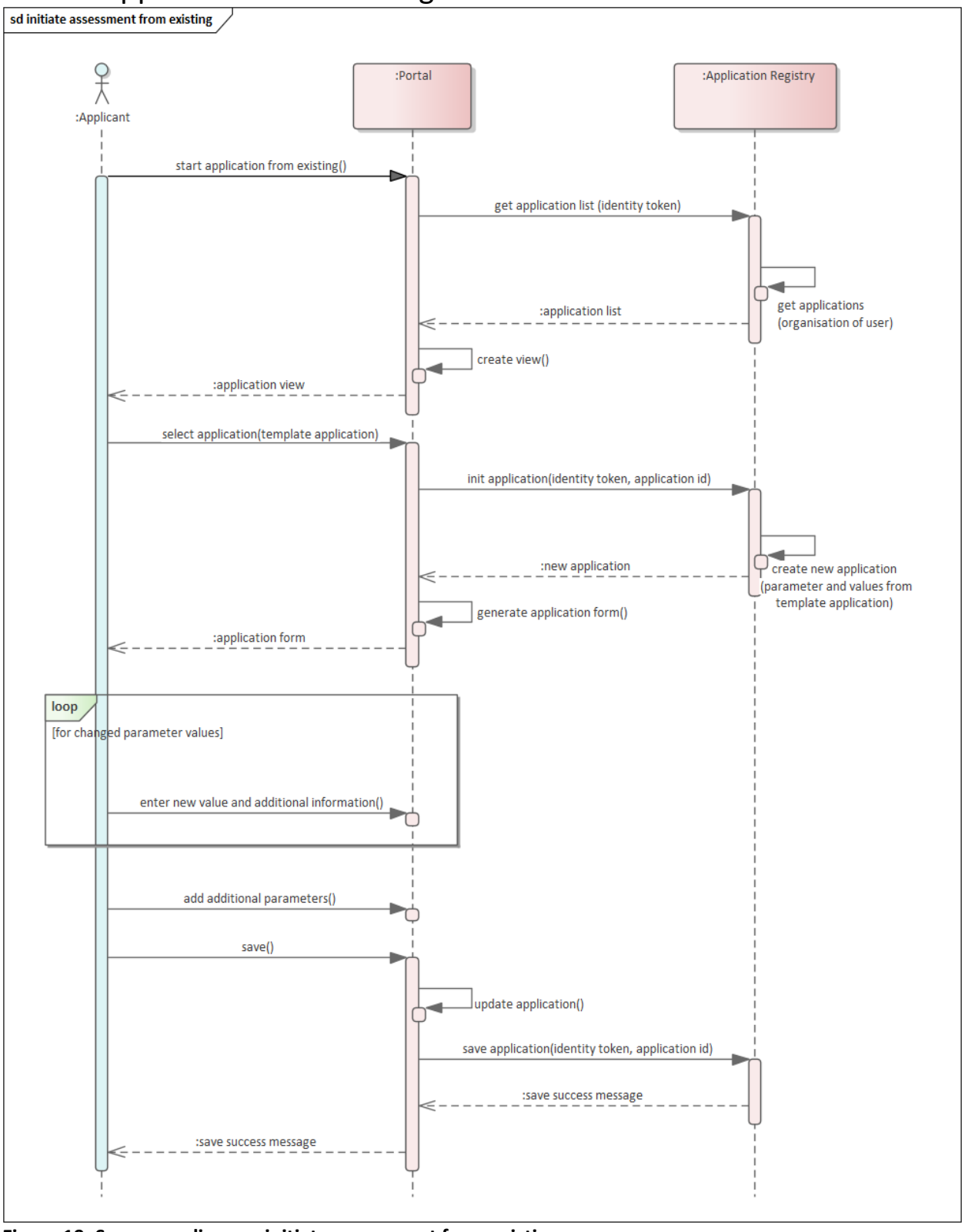

Figure 19. Sequence diagram initiate assessment from existing

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Aspect	Description
Use case Name	Initiate application from existing
Use case id	4
Description	The user initiates an application based on an existing application.
(Super use case)	-
Preconditions	• User is authenticated as applicant
Use case steps	9. User enters application page 10. User selects “new application” 11. User selects application as a basis. 12. System generates form according to selected application 13. User edits values in form and adds additional information 14. User adds additional parameters (optional) 15. User selects “release” 16. System saves application and returns save message
Expected result	• New application based on existing application is created

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Edit application

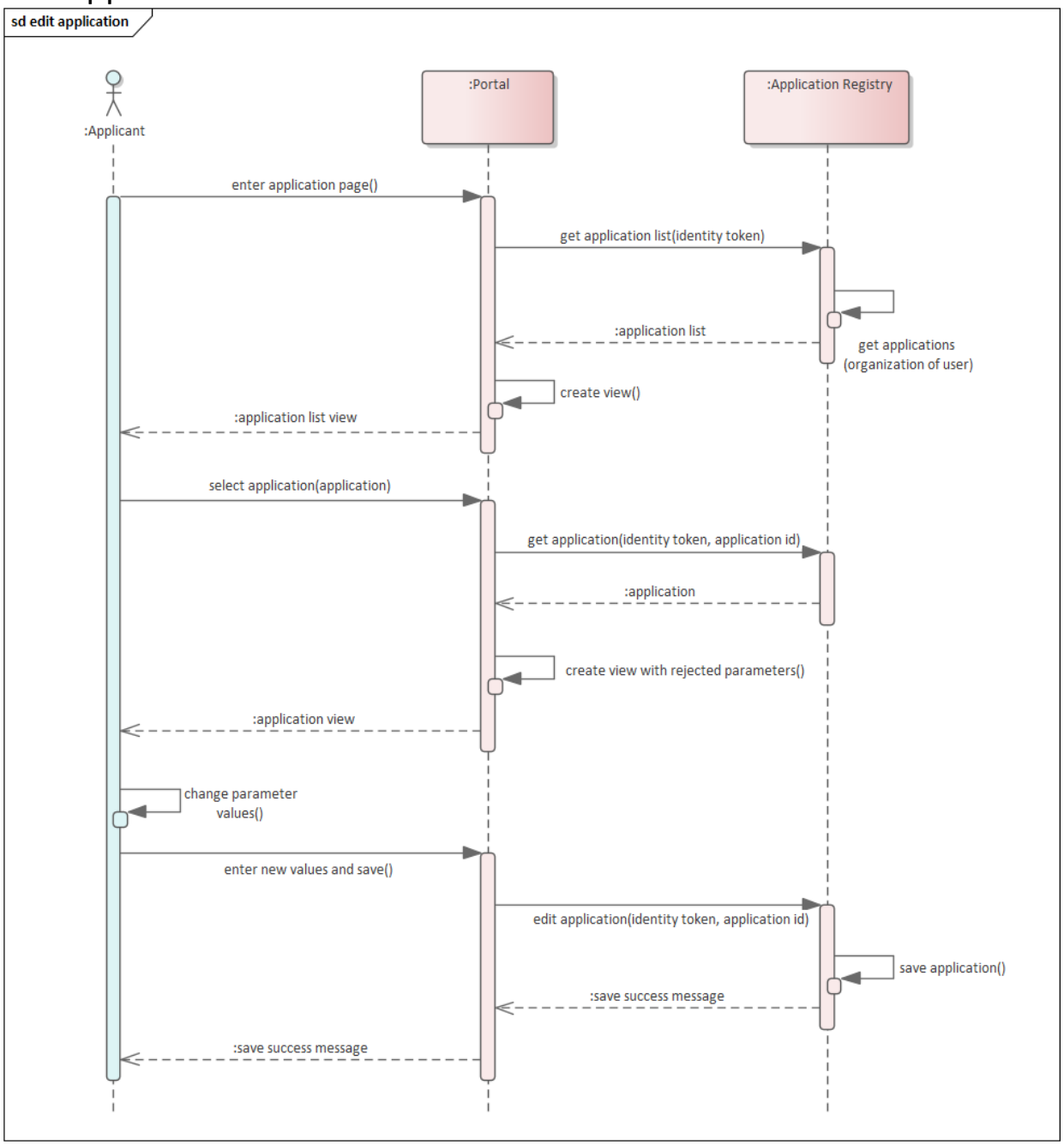

Figure 20. Sequence diagram edit application.

Aspect	Description
Use case Name	Edit application
Use case id	5
Description	The user edits the application and resolves assessors' comments.
(Super use case)	-
Preconditions	• Application is rejected by assessor • User is part of unit, which initiated the application

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Use case steps	1. User enters application page 2. System shows list of applications 3. User selects application 4. System shows application with comments of assessor, invalid values are highlighted 5. User changes preparation process (in real life) 6. User enters new values and saves 7. System saves new values with version history 8. Systems sends save success message
Expected result	• New values of application are entered and saved

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Review application

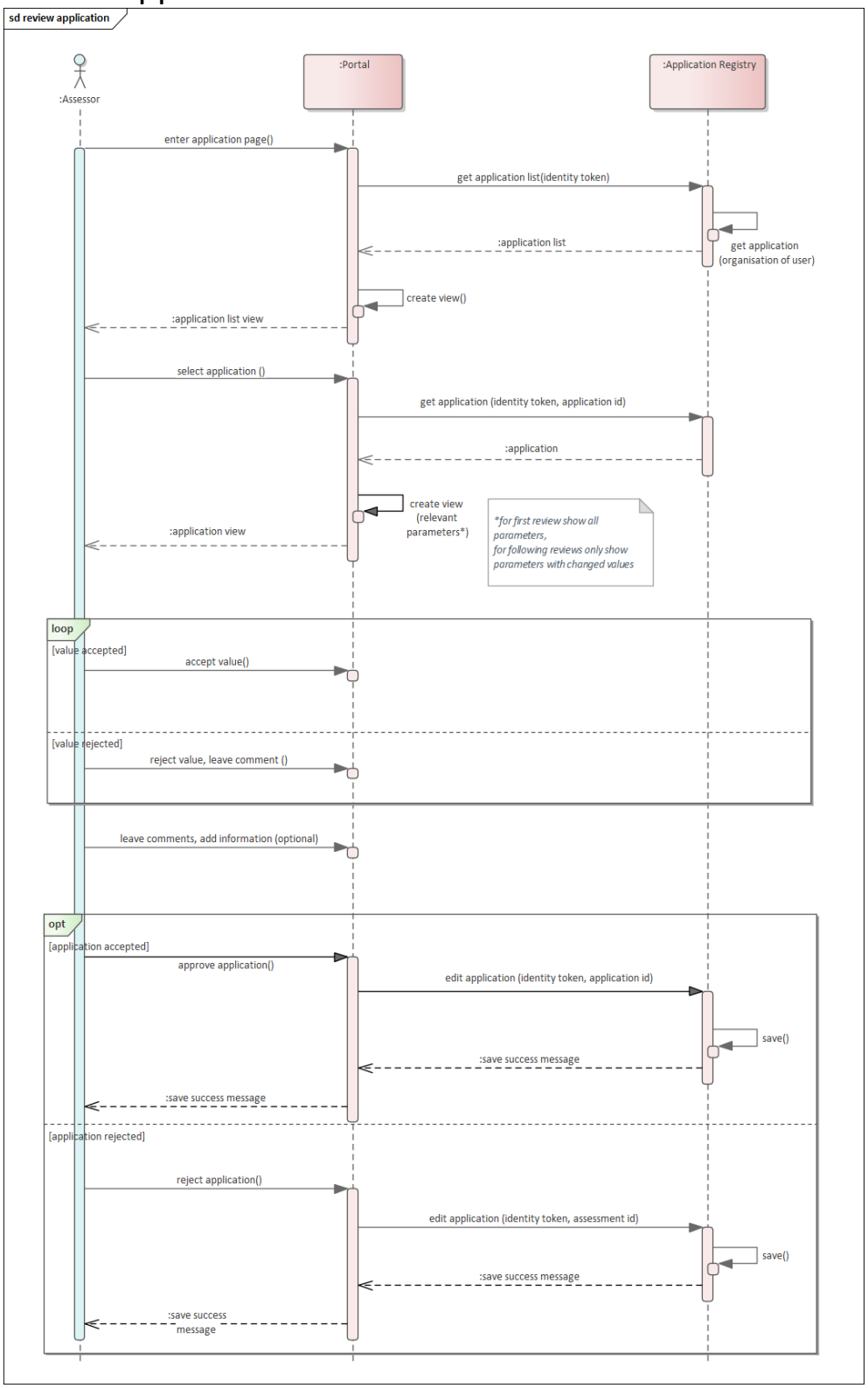

Figure 21. Sequence diagram review application.

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Aspect	Description
Use case Name	Review application
Use case id	6
Description	The assessor reviews released application.
(Super use case)	-
Preconditions	• Applicant initiated and submitted application • User is part of unit that is responsible to assess this application
Use case steps	1. User selects open application 2. System shows application view 3. For each parameter in application, User accepts value or reject value and leaves comments 4. User leaves additional comments (optional) 5. User approves or reject application 6. System saves approval or rejection and sends save success message
Expected result	• Application is approved/ rejected

View template parameters

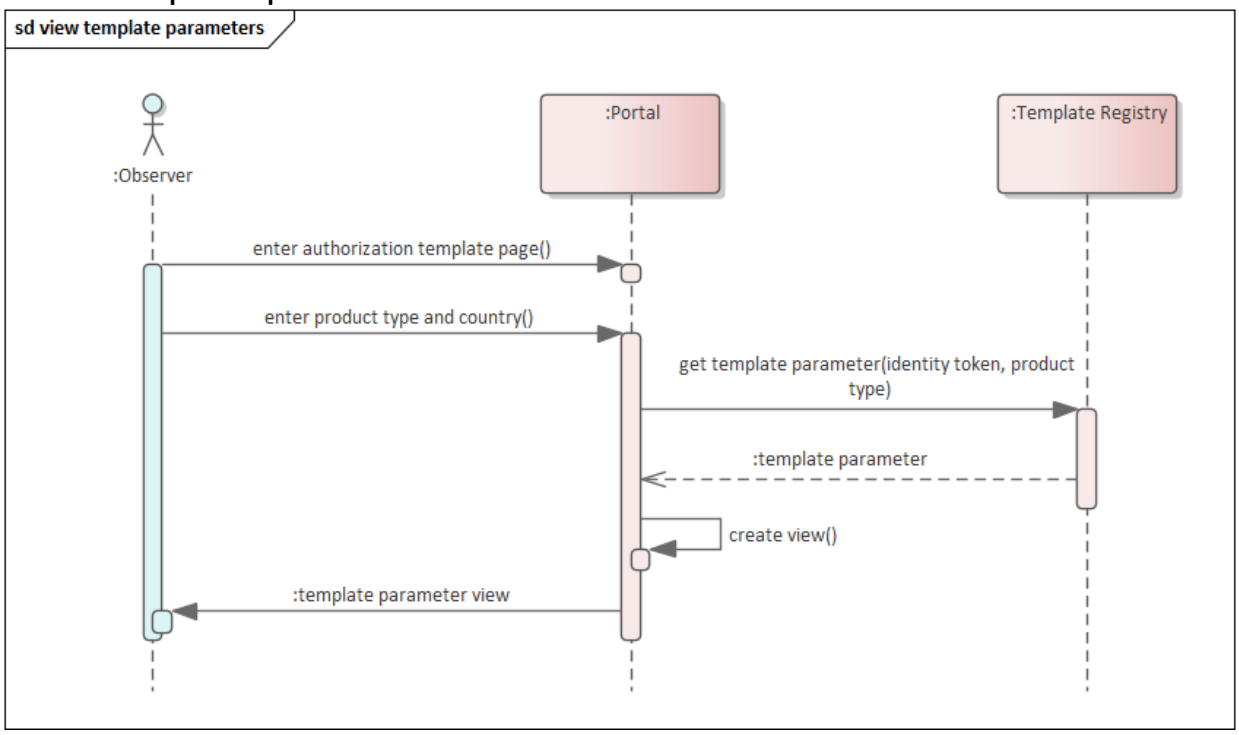

Figure 22. Sequence diagram view template parameters.

Aspect	Description
Use case Name	View authorisation parameters
Use case id	7
Description	The user views a template.
(Super use case)	-

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Preconditions	• User authorized to view authorisation parameters
Use case steps	1. User enters template management 2. User enters template 3. System shows authorisation parameter for selected template
Expected result	• View of authorisation parameter for selected template

Update template parameters

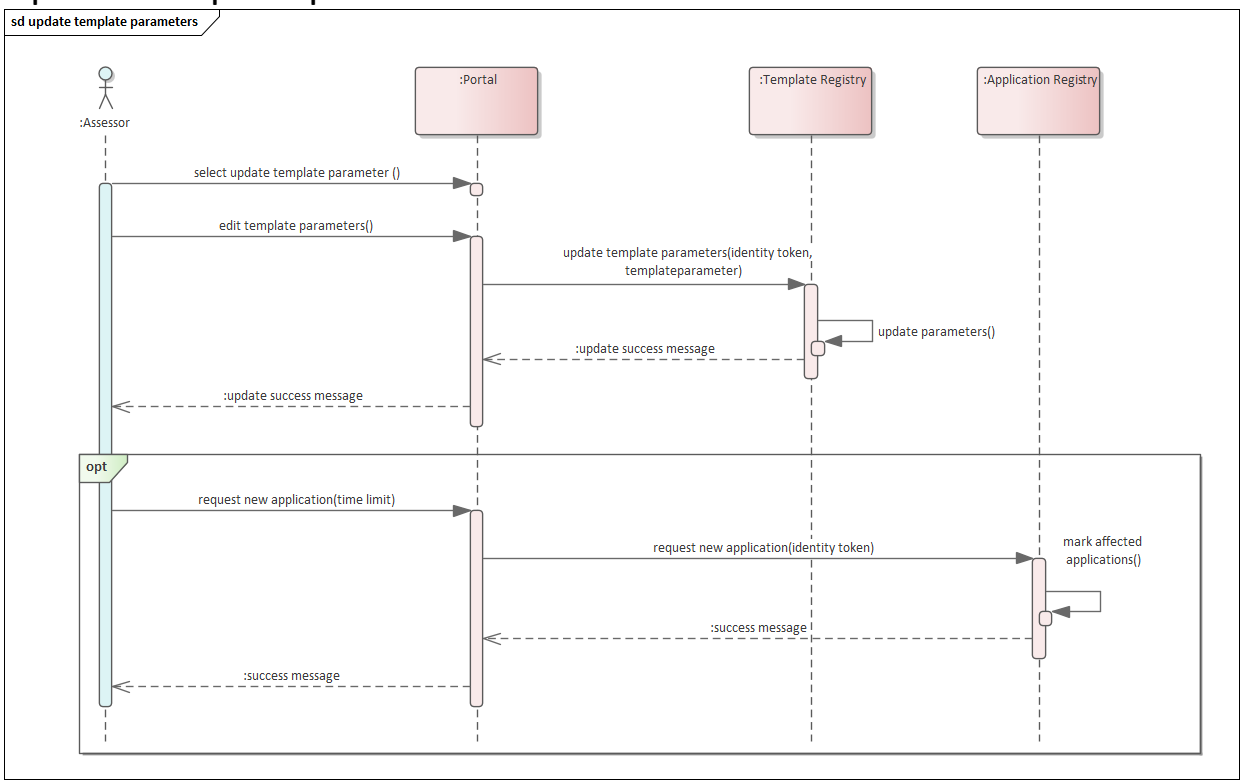

Figure 23. Sequence diagram update template parameters.

Aspect	Description
Use case Name	Update authorisation parameters
Use case id	8
Description	The assessor updates authorisation parameters of a template.
(Super use case)	-
Preconditions	• User is authorized to update authorisation parameters • User entered authorisation parameter page
Use case steps	1. User selects template 2. User updates authorisation parameters and confirms 3. System updates authorisation parameters 4. System sends success message
Expected result	• Updated authorisation parameters

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Cancel application

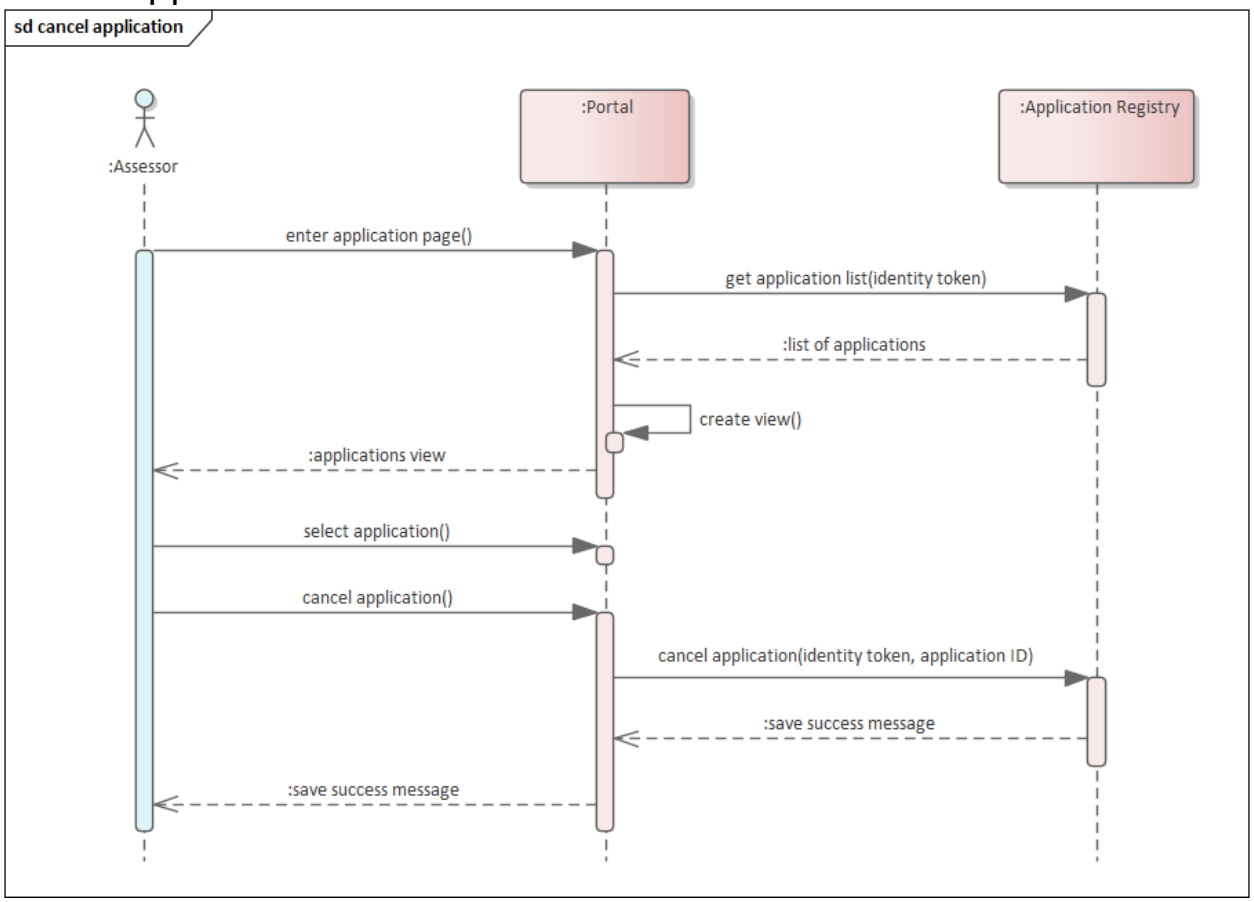

Figure 24. Sequence diagram cancel application.

Aspect	Description
Use case Name	Cancel application
Use case id	9
Description	The assessor cancels an application.
(Super use case)	
Preconditions	• Application has been started
Use case steps	1. User enters application page 2. System shows list of applications 3. User selects application 4. User selects “cancel application” 5. System marks application as canceled 6. System sends success message
Expected result	• Application is marked as canceled

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Create template

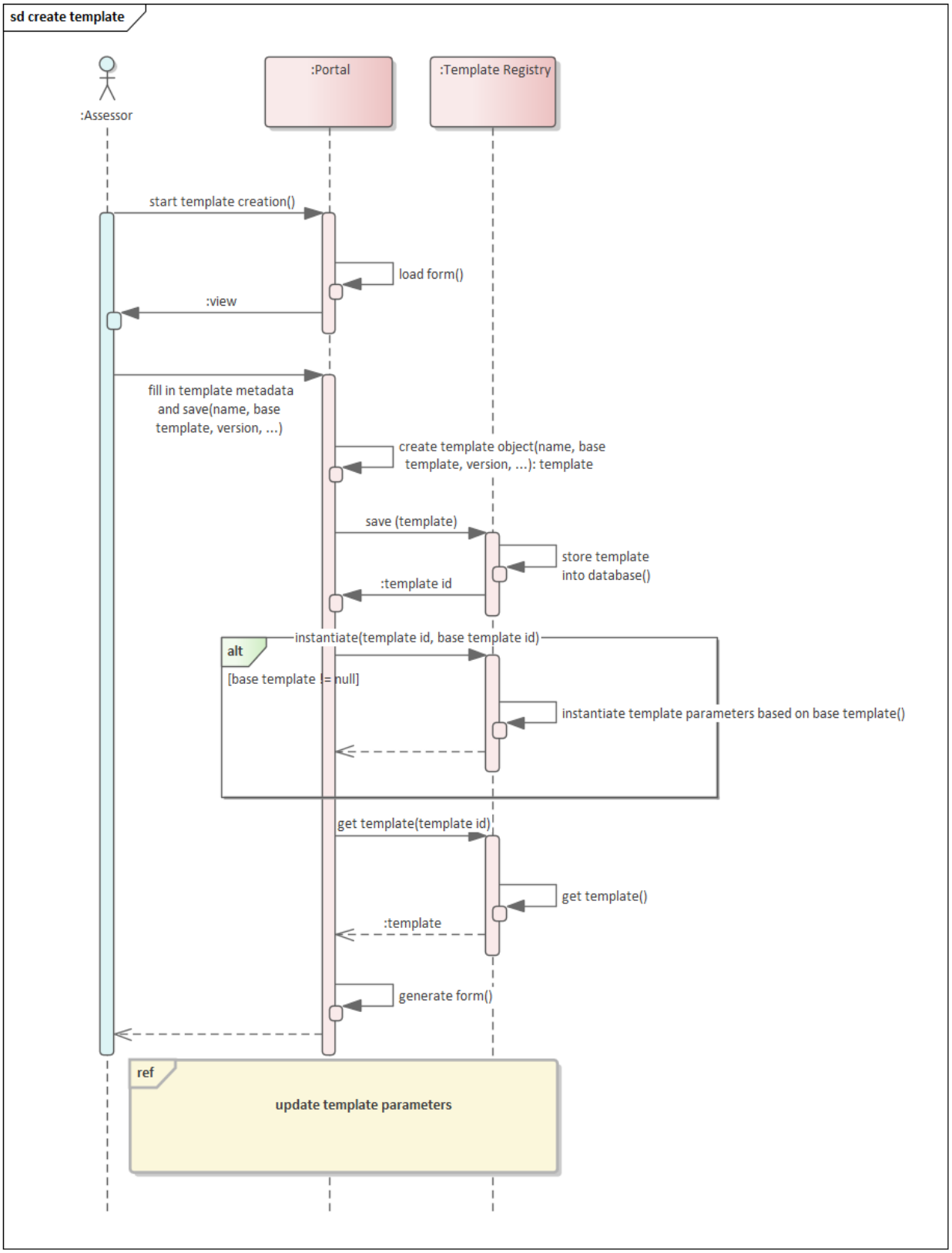

Figure 25. Sequence diagram create template.

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Aspect	Description
Use case Name	Create template
Use case id	10
Description	The assessor creates a template.
(Super use case)	
Preconditions	• Application has been started
Use case steps	7. User enters template creation form 8. User fills in relevant meta data and optional base template and confirms the creation 9. System creates initial template 10. If base template is chosen, the system initiates template parameters based on base template 11. System sends success message 12. User adds / adapts template parameters (see use case 8)
Expected result	• Template was created

11 Requirements

Requirements ID Provider

ID	Name	Description	Priority
ID_1	Authenticate	The user must be able to authenticate in order to use access-restricted functions from the portal.	MUST

Requirements Application Registry

ID	Name	Description	Priority
AR_1	Get application list	The user must be able to view a list of all existing application to which he is authorized.	MUST
AR_2	Get application by id	The user must be able to view application details by a given id.	MUST
AR_3	Init application	The user must be able to initiate a new application with the possibility to use a template or a previous application as a template for the new application.	MUST
AR_4	Save / Edit / Cancel application	The user must be able to save, edit and cancel an application and its values. This includes the status of application.	MUST
AR_5	Filter application by different parameters	The user must be able to view applications and to filter them (product type, ..)	MUST
AR_6	Request new application	The user must be able to request a new application for approval.	MUST

Requirements Template Registry

ID	Name	Description	Priority

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APR_1	Create template	The user must be able to create a template based on existing (inter-) national guidelines.	MUST
APR_2	Get template	The user must be able to view existing templates with the authorisation parameter for the process of approval	MUST
APR_3	Update template	The user must be able to change/update the authorisation parameter for the process of approval	MUST

12 Prototype of online platform

The following screenshots show how the described functions of the online platform appear in the demonstrator. For data protection reasons, the screenshots have been slightly modified (© for all screenshots FhISST).

Startpage - Applicant after Login

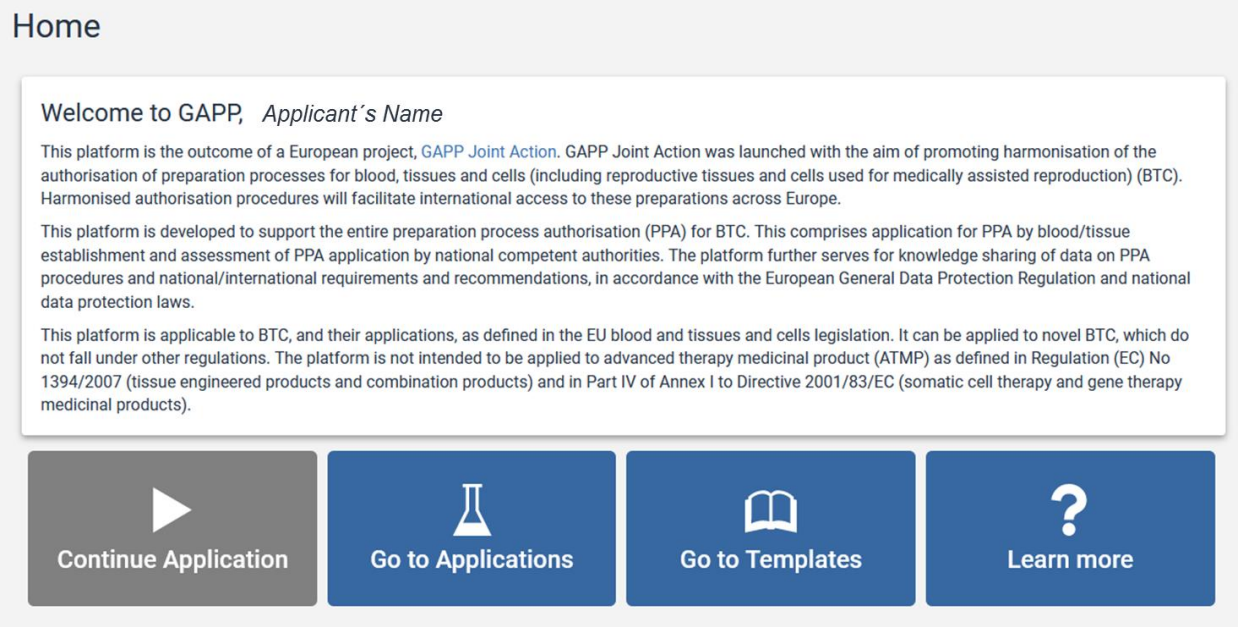

Figure 26. Start Page (© FhISST).

A Note for Risk Analysis

The Assessor is informed about the risk analysis.

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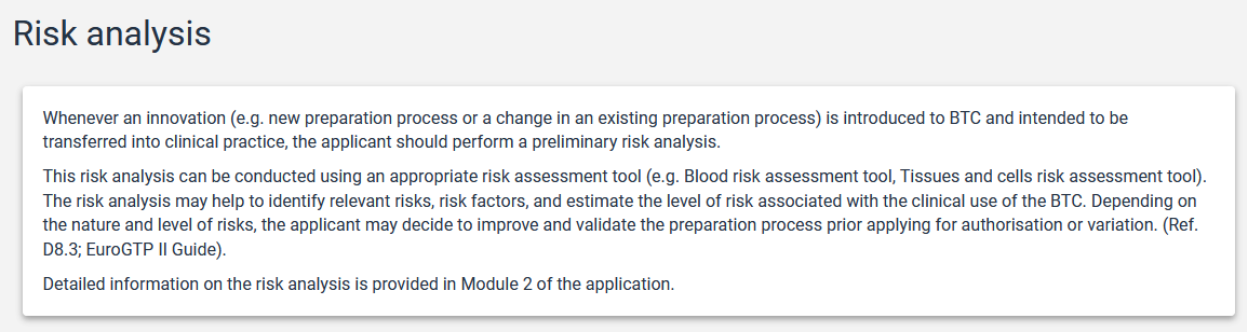

Figure 27. A Note for Risk Analysis (© FhISST).

Application Overview (Applicant View)

The screenshot gives an overview of the applications as seen by applicants. Applicants can initiate a new application process by (a) starting with an empty template or by (b) selecting a previous template. In the second case the values are copied. Started applications can be edited (c) and applications with requests for further information or changes can be responded (d).

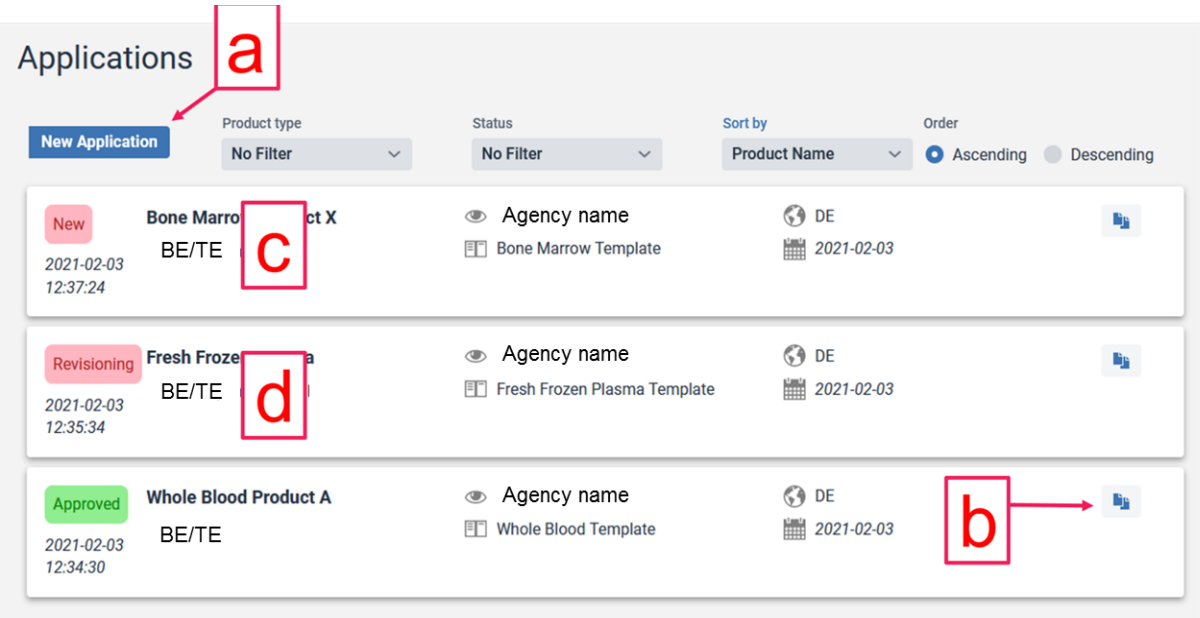

Figure 28. Application Overview (Applicant View) (© FhISST).

Template Selection (Applicant View)

When starting an application, applicants first have to choose a template for the application.

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Figure 29. Template Selection (Applicant View) (© FhISST).

Enter general information about the product (Applicant View)

After choosing a template the application form for entering application data is generated. The applicant must enter general information about the product.

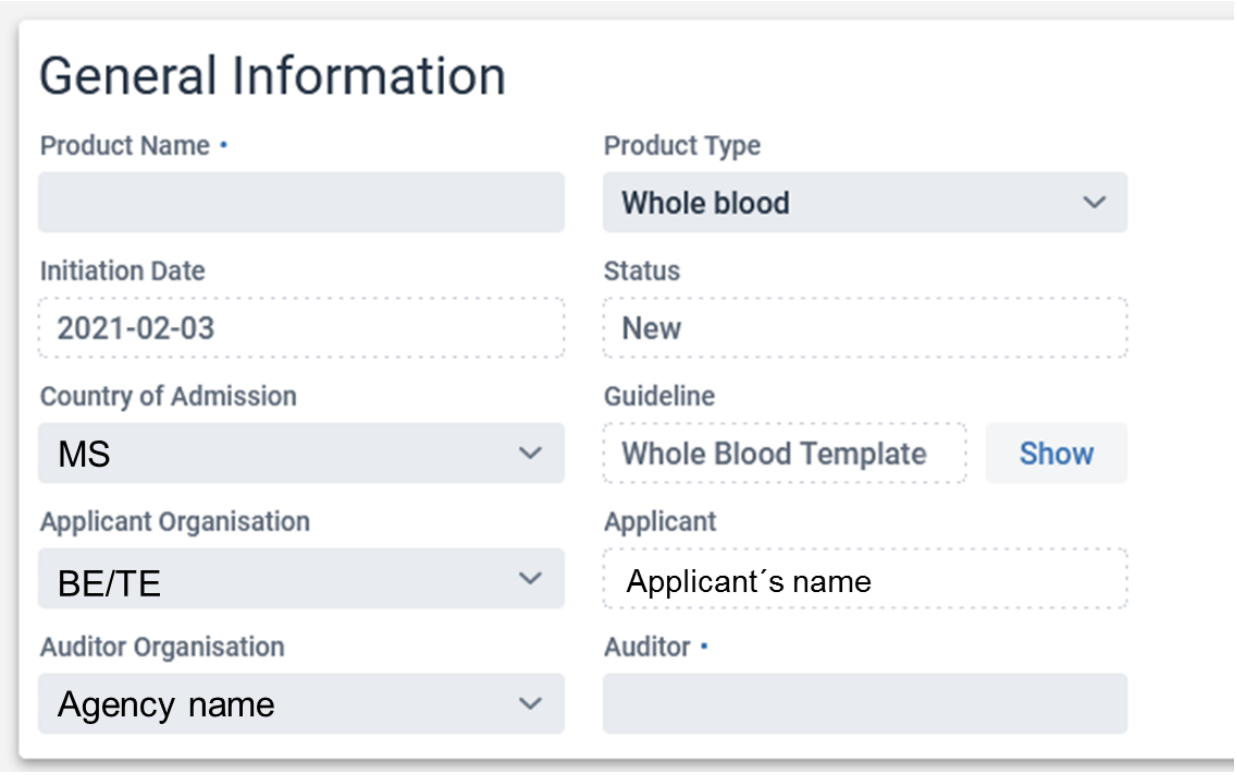

Figure 30. Enter general information about the product (Applicant View) (© FhISST).

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Enter Product Parameters (Applicant View)

The Applicant fills in all parameters and optionally records comments on the parameters.

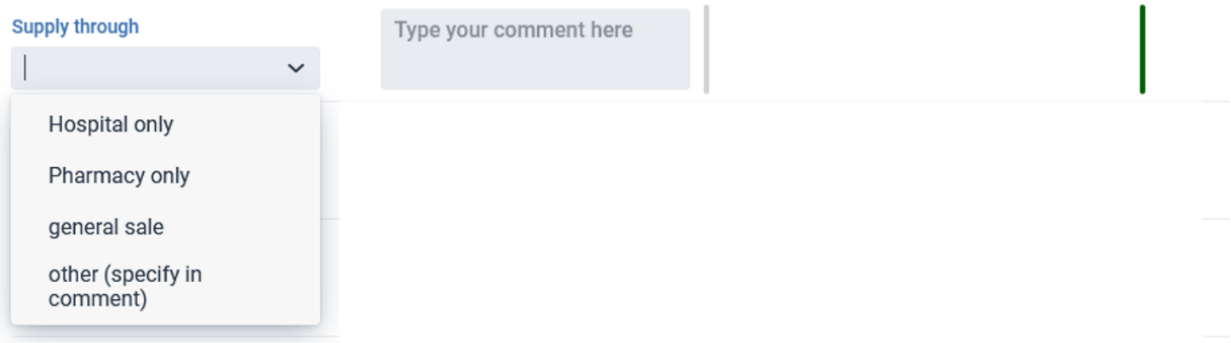

Figure 31. Enter Product Parameters (Applicant View) (© FhISST).

Parameter Assessment (Auditor View)

The assessor sees all applications that have been released for review in the GAPP tool in a list and can review them. A variety of options are available to him via the user interface. In addition to checking and accepting parameters, the assessor can add comments or request more information for evaluation.

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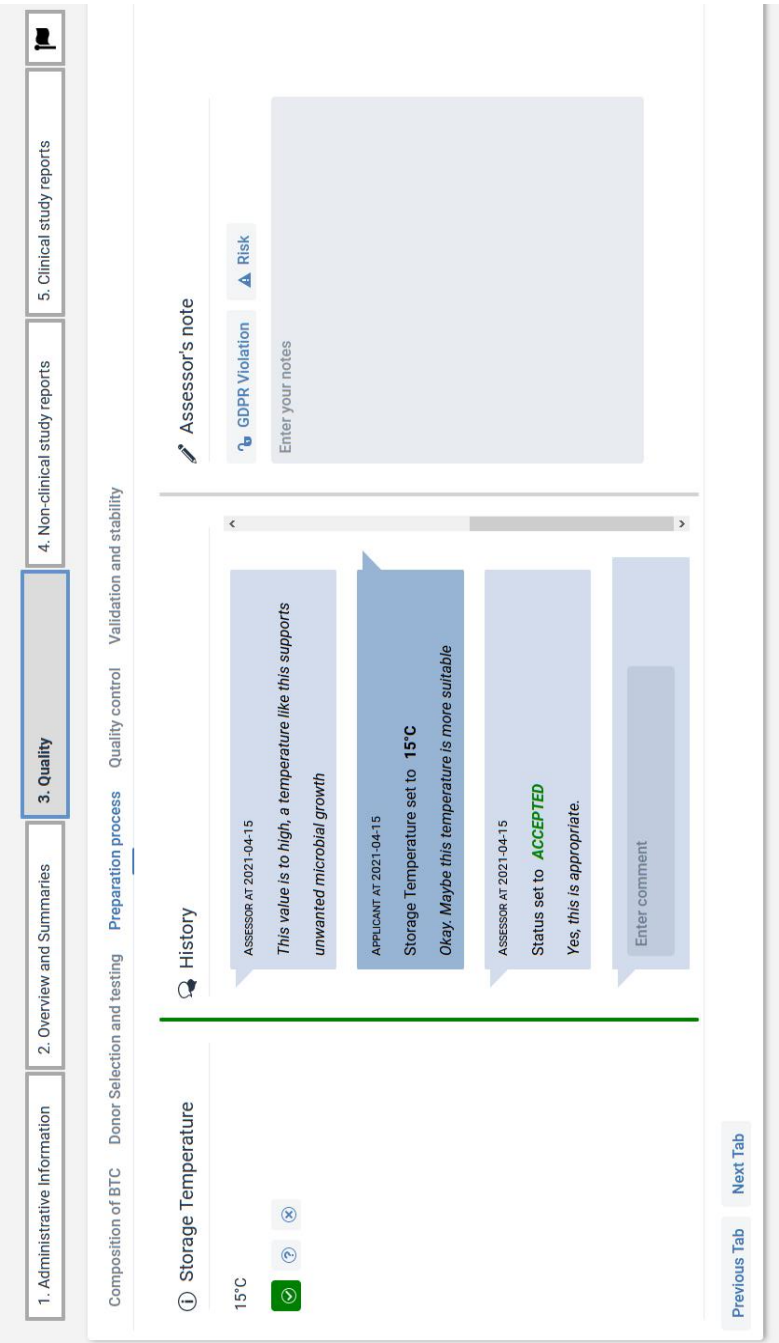

Figure 32. Parameter Assessment (Auditor View) (© FhISST).

National and International Requirements

Users of the GAPP tool can view national and international parameter requirements in comparison.

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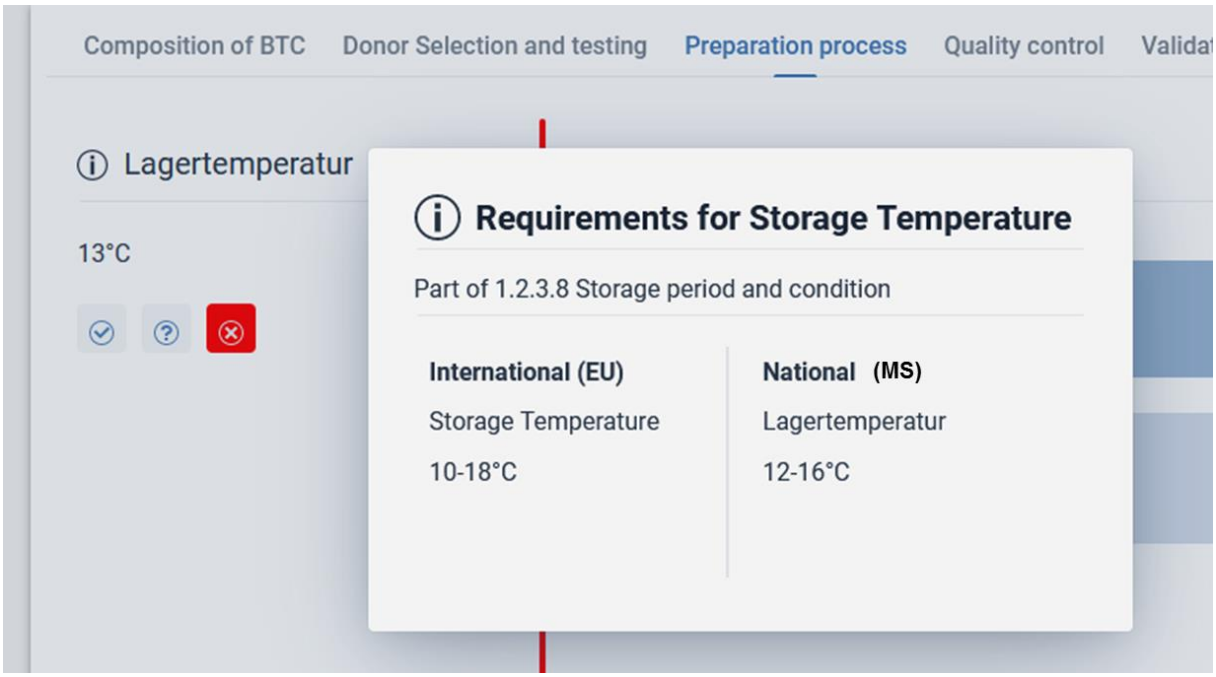

Figure 33. National and International Requirements (Auditor and Applicant View) (© FhISST).

International Code and Description of Parameter (Authorized Institution)

An authorized committee or organization edits international parameters. International requirements for parameters can be set.

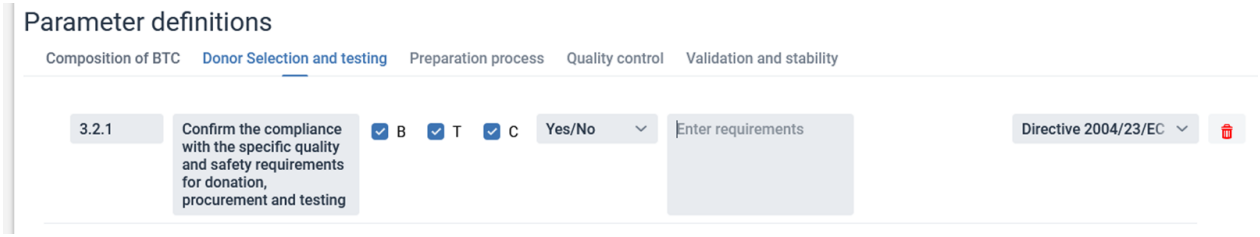

Figure 34. International Code and Description of Parameter (Authorized Institution) (© FhISST).

National Adaption and Translation of Parameter (Authorized Institution)

A national committee or organization adapts international parameters to a national level. National requirements for parameters can be set (can differ from international requirements)

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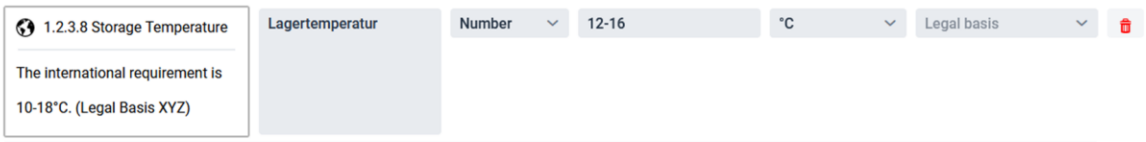

Figure 35. National Adaption and Translation of Parameter (Authorized Institution) (© FhISST).

13 Lawful processing of personal data

The European Commission has enacted a series of Regulations and Directives, to strengthen individuals' fundamental rights regarding processing of personal data. The GDPR sets the legislative framework for personal data protection in the EU and has binding effect in all Member States. By protecting the person rights and ensuring the cross-border data exchange of personal data within the EU (GDPR Article1) the GDPR aims to contribute towards freedom, security, and justice. Personal data means „any information directly or indirectly relating to an identifier of identifiable natural person" (Article 4). The GDPR defines processing as any operation, which is performed on personal data. The GDPR defines data protection principles in Article 5, which are essential for the lawful processing of personal data: (1) Lawfulness, fairness, and transparency, (2) Purpose limitation, (3) Data Minimization, (4) Accuracy, (5) Storage limitation, (6) Integrity and confidentiality.

Article 6 of the GDPR defines processing of personal data as lawful if at least one of the following six circumstances are met:

- The data subject gives consent.
- Processing is necessary for the performance of a contract to which the data subject is party or to take steps at the request of the data subject prior to entering a contract.
- Processing is necessary for compliance with a legal obligation to which the controller is subject.
- Processing is necessary to protect the vital interests of the data subject or of another natural person.
- Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.
- Processing is necessary for the purposes of a legitimate interest pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject, which require protection of personal data, where the data subject is a child.

Processing of special categories of personal data such as health data is prohibited unless one of ten condition, which are defined in Article 9 are met (for example with explicit consent of the person or if processing relates to personal data which are manifestly made public by the data subject).

Data security is a key requirement of the GDPR when processing personal data. To avoid unlawful processing, loss, destruction or damage data controllers and processors must implement appropriate technical and organizational measures based at least on the state of the art. The GDPR suggests concrete

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measures. Table 10 sums up relevant security goals and proposes technical measures for establishing knowledge exchange within the EU.

With regard to electronic identification and trust services, the eIDAS regulation can be used. eIDAS stands for electronic identification, authentication and trust services. This regulation establishes the legal structure for the use of electronic identification and trust services (i.e. electronic signatures, seals, time stamps, registered electronic delivery and website authentication) in the EU. Cross-border electronic interactions are based on a common foundation and ensure an appropriate level of security when the eIDAS regulation is consistently applied.

Table 10. Security goals and technical measures for exchange of information within the EU.

Security Goal	Possible Technical Measures
Confidentiality & Access Control: Assure that data are not accessed by not authorized people.	• Identity management • Authentication management • Authorisation management • Transport Encryption • Policy Enforcement • Physical security (Data Storage Encryption)
Integrity & Authenticity: Avoid that data are lost. Avoid that data are corrupted or altered.	• Data Minimization • Use of Qualified Digital Signatures and Timestamps • Certification of CA Software which are part of the data exchange • Verification of Digital Signatures • Backup of information • Use of checksums for data transfer
Availability: Prevent unauthorized withholding of information or resources.	• High availability of storage systems • Prohibition of Data Erasure • Physical Protection • Computer Redundancies
Traceability & Non-Repudiation: Track the origin (source and author) of data. Assure that an author cannot successfully dispute its authorship or the validity of an associated contract.	• Auditing of data processing transactions (Logging) • Confirmation Procedures (handshaking), network authentication • Session-Management • Data Provenance Tracking • Technical verification of transactions • Verification of Digital Signatures

In addition to technical measures, organizational measures must be taken to ensure data protection and data security.

Training of users with regard to data protection: Users must be trained on how to use the tool in accordance with data privacy regulations. An important aspect is to explain which data may be entered into the system. Patient and donor data (fully personalized data with name, place of residence, date of birth, preferably together with medical history, etc.) must not be entered into the database.

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Discussion and conclusion

Summary:

The main task of WP9 is the development of a concept of an online platform for BTC authorisation, which can be based on the title of the GAPP Joint Action: “Facilitating the authorisation”. In order to support CA as well as possible in authorisation processes, the platform must be efficient in use. User guidance, usability, and the information provided are of high importance. The advantages of a digital system must be used optimally.

The tool allows to share information and data on the assessment of PPA applications in the field of BTC between the EU MS CA. Therefore, it was considered to design an online platform with the inclusion of as an application and assessment tool.

A basic structure for the application procedures, the PPD structure (derived from the CTD), was first developed. This ensures that all relevant aspects for BTC authorisation are taken into account. The complete different nature of blood, tissues/cells, HSC and MAR required flexibility and differentiation of the PPD structure. These four categories are subdivided into subcategories and, if necessary, sub-subcategories in order to be able to offer templates based on international and national requirements in a reasonable depth of differentiation according to the results of WP6–8, as well as EDQM Tissues and Cells Guide and EDQM Blood Guide. On the national level, the proposed templates can be adapted to the specific national requirements by removing unneeded aspects, by translating them into the own national expert language and by allowing to provide own information (and own templates).

Despite possible adaptations and differentiation, the underlying PPD structure will allow for detection of specific information in the procedures of all CA.

In addition to the adaptability of the content, the efficiency and usability of the platform is important. Usability is essentially determined by the design and functions of the platform.

The two main user groups are applicants and assessors.

The applicant is guided through the application process using the PPD structure. The PPD structure suggests that the navigation be presented through two levels. The top level is defined by modules 1 to 5 of the PPD structure (Figure 32). The second level is defined by the PPD level below (Figure 32). Further sublevels are presented on a worksheet that can be scrolled up or down. If a worksheet becomes too large, it is divided into user-friendly parts that can be moved between using a forward arrow or backward arrow (Figure 32).

Design:

In the design, care was taken to ensure that the presentation is clear and uncluttered, and that functional elements with high recognition value are used for interaction with the user. Functional elements must have a uniform design (links always function as links and are clearly recognizable as such, buttons that look the same always have the same function, different button designs are used for different functions).

The presentation aims to ensure that the online platform is largely self-explanatory and does not require a high effort for learning and familiarization. Explanations for functional elements are given as mouse-overs. All content, must be formulated clearly, precisely and in a way that is easy to understand.

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Functions for the application process:

A progress indicator for application is not given, as an application can be processed at any point and even incomplete applications can be submitted to CA for assessment. However, for better orientation, it is made visible which part of the application the applicant or assessor is currently processing.

Wherever possible, the applicant is provided with comment fields to communicate information that can only be given as a textual description to the assessor. These fields can also be used to contact the application evaluator to clarify any questions the applicant may have.

The online platform allows information once entered to be reused to the extent possible. For example, applicants can use their own applications already stored in the system as templates for new applications or variations.

The "empty" templates themselves are pre-filled with national and international specifications to reduce the input effort. For Variations, already authorized applications can be modified at the relevant points for submission.

Functions for assessment:

The assessor has the option to accept or reject information provided by the applicant, or to formulate questions, if necessary. Accepted or rejected information is made visible to the applicant. Also visible to the applicant shall be questions, follow-up requests, notes, and comments by the assessor. Such messages may be entered at any point in the application to allow the applicant to clarify and complete their application. Responses may be made by the applicant by modifying the information already entered or by query, note, and comment, to which the assessor may respond again until the issue is resolved. This communication is implemented in the form of a "chat function" on the online platform.

To further support the assessment, an area is set up that is only visible to the assessor. Here assessors have the possibility to enter remarks, reminders for themselves. Of particular importance is the function to identify, comment on, and list risks for benefit-risk assessment.

Benefits of the approach:

The templates prepared guide the applicant in a structured way through the entire application process and clarify at each point what information is required and in what depth. Pre-entered information - if it matches the applicant's procedure - can be taken over directly to reduce the input effort. Other applications submitted by the applicant can be used as templates as well.

By using a common database, the applicant and the assessor always have the same data and information basis to which both can always refer.

The flexibility of the online platform makes it possible to map special national procedures. For example, all-national approvals for certain BTC can be made available as a template for the applications of individual BEs/TEs. Provided that national rules allow it, applicants can fill in individual parts of a PPD (e.g. module section donor testing) in order to refer to such parts repeatedly in other application procedures.

Assessors can assess (accept, reject, request further information) any item directly in the PPA application. Open questions can be clarified with the applicant in a kind of "chat" directly at the affected point in the

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application. Identified risks can be marked and commented on for later benefit-risk assessment. Flagged risks can be compiled in the form of a list to be used for benefit-risk assessment.

Personalized donor and patient data are not required for benefit-risk assessment and are not allowed in an application. Such data can be flagged as a data breach at the affected site to prompt applicants for deletion. A listing helps track the removal of the offending GDPR violations. A separate comment function allows to enter (personal) remarks at any point that cannot be seen by the applicants, e.g. reminders.

Changes to approved applications are made by the applicant directly in approved PPDs and submitted as a change. The assessor is guided directly to the changes in the documentation and can assess them directly there without any search effort.

National customization allows the level of detail to be defined, as well as the use of national expert language for the various categories of blood, cells, tissues, and MAR to enable clear and efficient communication between applicants and assessors.

The templates are largely self-explanatory and require no training. Communication from applicant to assessor is facilitated by omnipresent text fields, allowing comments, explanations and questions to be passed at any point in the application.

General international and national requirements and information are available to applicants and assessors in the same way. Assessors can additionally obtain detailed information on all national and international approved applications, templates, requirements and regulatory requirements.

Effort:

The effort required to program and set up an online platform at the EU and national levels is likely to be considerable, but cannot be quantified. However, the principal programming, the general feed-in of the international requirements and the national customizations have to be done only once, and adaptation to changing requirements as required in continuous follow up.

The international part of the online platform (program, PPD structure, templates) must be continuously maintained and kept up to date. The effort required for this is likely to be limited to minor interventions in the event of regulatory changes. No statement can be made about the adaptation of the software for instance to future operating systems, for example.

Maintenance at the national level comprises the national implementation of new EU requirements, which is provided on a central EU server and can be obtained/downloaded from there. The implementation of new national requirements is likely to be limited to minor interventions.

Thorough validation studies after establishment of the online platform and after software updates must be scheduled.

Such an online platform can support and promote digitization and digital information management in the field of PPA of BTC. Setting it up as an international platform that can be adapted for national purposes with a high degree of flexibility allows for cost-effective development and deployment.

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Conclusions:

The concept is not just an application form. In fact, it is first and foremost a basic structure (PPD structure based on CTD) that can be used independently of the respective national regulations for the authorisation of BTC. It includes the different categories of blood, cells, tissues and MAR, but it is flexible enough to be adapted not only to these different categories, but also to the different national requirements of the EU MS. Despite this high flexibility, it supports an efficient knowledge sharing on all applications authorized in this platform.

The proposed online platform enables the sharing of information about the different national procedures and thus promotes harmonization by example.

In the course of the joint action, various requirements for the online platform were raised: Online platform for knowledge sharing, application tool, assessment tool, completeness, efficiency, no new requirements, cover all national procedures. The present concept shows that the different requirements can be implemented and the proposed platform can still be flexible enough to cover a wide variety of national authorisation procedures for BTC/MAR: It provides a framework to map all possible requirements in a complete and structured way, which can be easily adapted. The concept emphasizes the most efficient work for applicants and assessors through a focus on usability and user-friendliness, excessive data re-use possibilities and the maximum possible flexibility and adaptability of the tool.

Outlook:

The present concept focuses on the main functions (application and assessment) of the online platform. Some technical features, e.g. printing and downloading information from the platform, or e-mail-notification of applicants and assessor if action is needed, were not described since they are standard techniques.

The request from the GAPP consortiums for a chat room for assessors linked to the platform can also only be passed on as a future task.

If this concept is implemented, a database with valuable data and information might emerge over time, therefore the development of analysis tools to evaluate this data and information will be useful.

It would also be important to integrate a separate translation tool into the platform so that the required confidentiality can be guaranteed for translations.

During the GAPP Joint action, the combination of the platform with other tools was suggested. In fact, it seems helpful to aim for an overall software solution that combines various individual solutions. For example, EuroGTP II and the platform could represent two stages of an application process for a BTC instead of acting as two stand-alone systems linked only by hyperlinks. Positive authorisation results could then in turn be automatically transmitted to an integrated publication platform. A unified, user-friendly interface for different tools could promote more efficient work with these tools.

Such a platform must be constantly adapted in its life cycle, also to achieve improvements in handling, layout and functions. Ultimately, the acceptance by EU MS will determine whether such a platform can be successfully used to share information and data on known and new BTC and show whether it is a useful and helpful tool for authorizing BTC.

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ANNEX 1 Common format for preparation process dossier for blood, tissues and cells

Tab 1 heading on the platform ribbon	Tab 2 heading on the platform ribbon	
Administrative information	1.1 Cover letter	
	1.2 Application form	1.2.1 Declaration
		1.2.2 Type of application 1.2.2.1 Type of submission 1.2.2.2 Type of application
		1.2.3 PPA application particulars 1.2.3.1 Given name 1.2.3.2 Active substance(s) 1.2.3.3 Qualitative and quantitative composition 1.2.3.4 Preparation characteristics 1.2.3.5 Summary information about processing 1.2.3.6 Dosage form 1.2.3.7 Clinical particulars 1.2.3.8 Packaging and pack size 1.2.3.9 Storage period and condition
		1.2.4 Legal supply
		1.2.5 Applicant/PPA holder and contact persons 1.2.6 Processing and testing sites 1.2.7 Other sites/contact persons
		1.2.8 Annexed documents
	1.3 Accompanying document and labelling	1.3.1 Accompanying document 1.3.2 Labelling 1.3.3 Other
	1.4 Experts	1.4.1 Quality 1.4.2 Non-clinical 1.4.3 Clinical
	1.5 Vigilance	1.5.1 Vigilance system 1.5.2 Risk-management system
	1.6 Additional information	
Overview and summaries	2.1 General information	
	2.2 Risk analysis	2.2.1 Risk analysis 2.2.2 Plan for collecting post-authorisation data
	2.3 Overview and summaries	2.3.1 Quality 2.3.2 Non-clinical

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		2.3.3 Clinical
Quality	3.1 General information	
	3.2 Donor selection and testing	3.2.1 Donor selection criteria 3.2.2 Donor/donation testing 3.2.3 Materials 3.2.4 Equipment
	3.3 Processing	3.3.1 Processing and in-process controls 3.3.2 Materials 3.3.3 Equipment 3.3.4 Facilities
	3.4 Quality control	3.4.1 Quality attributes for quality control prior to release 3.4.2 Quality control procedure 3.4.3 Materials 3.4.4 Equipment
	3.5 Packaging system	3.5.1 Description of packaging system 3.5.2 Summary and conclusion of packaging system
	3.6 Validation and stability	3.6.1 Quality attributes for validation 3.6.2 Validation procedure 3.6.3 Summary and conclusion of validation 3.6.4 Validation reports 3.6.5 Materials 3.6.6 Equipment
Non-clinical reports		4.1 Non-clinical reports
Clinical reports		5.1 Clinical reports

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ANNEX 2 Template for preparation process dossier for blood, tissues and cells

Table 10. Terms used in tables concerning modules 1–5.

Term	Description of term
Category	"Category" as a column heading indicates the relevance of information for blood (B), tissues/cells (TC), hematopoietic progenitor cells (HPC), medically assisted reproduction (MAR), or all four categories (all). This differentiation is made to provide applicant only with parameters and requirements specific for the preparation for which the PPA is applied for. Possible further indication for relevance of information (such as type of submission (e.g. change, renewal) is also stated in this field.
B	Blood components
TC	Tissues and cells, except of hematopoietic progenitor cells and reproductive cells used for MAR
HPC	Hematopoietic progenitor cells
MAR	Medically assisted reproduction
Description/instruction	"Description/instruction" describes the information the applicant should provide. Assistance and guidance (definitions; notes; links to directives, databases or other GAPP documents) given to applicant are indicated in this field.
Parameter	"Parameter" determines the actual parameter (e.g. name, address) to be provided by the applicant. In case of "drop down" or "check box", the value set of a drop down/check box are listed in Parameter. Sublevel of "drop down" is indented.
Data field type	"Data field type" indicates what type of information (text, file, etc.) the applicant can submit.
Legal basis	"Legal basis" refers to the legislative basis to be followed for providing specific information.
Additional reference	"Additional reference" refers to any other (non-legal) reference documents for providing specific information (e.g. Technical Annexes 1–3, EuroGTP II Guide). These documents may provide additional information and guidance for filling in the application dossier.
Links	Links to templates to be downloaded, filled in and uploaded, links to websites, links to reference documents, and links to other sections of the application form are marked blue.
Prefilled fields	Prefilled information that the applicant can edit is provided in grey in templates.
Templates	Templates/example templates illustrate how specific information is intended to be structured or could be requested by competent authority in the online platform.

Other, please specify	Whenever the option "other, please specify" or a parameter followed by "please specify" is selected by the applicant, a text box appears to allow specification. ☒ Other, please specify Enter text

Attachments	Whenever an attachment is uploaded, a descriptive file name is either already defined (e.g. Curriculum vitae) or provided by the applicant. This will allow more precise searching of specific attachments in the online platform. The applicant may provide several (e.g. 0–∞) or limited number (e.g. 1) of attachments. Curriculum vitae [Upload file] [Descriptive file name] [Upload file] [Additional information, if applicable]

Module 1 – Administrative Information

1.1 Cover letter

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
	all	Note: For change application, provide a detailed description of proposed changes. Justification of changes and alternative therapies or BTC (if any) should be included.		text box file box (1)		

1.2 Application form

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
1.2.1 Declaration	all	Provide declaration		file box (download-upload) (1) (example of template is provided in Figure 24)		
		Attach a letter of authorisation for communication/signing on behalf of the applicant		file box (1)		
		Attach a proof of establishment (e.g. certificate of registration) of the applicant, if appropriate		file box (1)		
		Attach a proof of payment for relevant fees paid, if appropriate		file box (1)		

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
		Declaration Description of BTC: _____ Applicant: _____ Address: _____ _____ _____ _____ It is hereby confirmed that all existing data, which are relevant to the quality, safety and efficacy of the BTC, have been supplied in the dossier, as appropriate. On behalf of the applicant _____ Signature(s) _____ Name: _____ Place, date ☐ Letter of authorisation for communication/signing on behalf of the applicant is attached. ☐ Proof of establishment (e.g. certificate of registration) of the applicant is attached, if appropriate. ☐ Proof of payment for relevant fees paid is attached, if appropriate. **Figure 24. Example of template for declaration**. Adapted from NTA, Vol. 2B-EU Module 1.2[5]				
1.2.2 Type of application	all	Type of submission:	• PPA application • renewal • change	(drop down (1) (values selected when starting the application, cannot be changed in this section))		WP5 Guide

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
				• Selection of “PPA application” activates “according to” (see below) • Selection of “PPA application” activates “Type of application” (see below)		
		in accordance with:		drop down (1) (values of drop down laid down at national level according to national legal basis for application)		
	all (PPA application)	Type of application:	• Full application (complete dossier) • Bibliographic/well-established use application (literature only) • other, please specify	drop down (1)		
		Additional information, if applicable		text box		
	all (renewal)	Date of current authorisation:		(prefilled according to the authorisation, cannot be changed in this section)		
		Expiry date of authorisation:		(prefilled according to the authorisation, cannot be changed in this section)		
		Additional information, if applicable		text box		
	all (change)	Type of application:	• minor change (administrative change, change with no effect on	check box (0–n) • Selection of “minor change” activates “For		

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
			quality or safety of the BTC) • major change (change with potential effect on quality or safety of the BTC)	minor change, add the date of implementation" (see below)		
			• single change • multiple changes	drop down (1)		
		For minor change, add the date of implementation, if applicable		datetime		
		For minor change, select all changes concerned	• administrative change • name of the BTC • name of PPA holder • address of PPA holder • name of processing/testing site • address of processing/testing site • change, addition or deletion of processing/testing site • minor change in the preparation process • change in the quality attributes • other, please specify	check box (1–n)		
		For major change, select all changes concerned	• urgent safety concern • safety • quality	check box (0–n)		
			• clinical indication • donor selection • donor testing	check box (1–n)		WP5 Guide

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
			• procurement • processing • quality control • storage • distribution • other, please specify			
		Provide a description of the proposed change(s)		text box		
		If the change affects more than one authorisation, specify other authorisations concerned		text box		
		Additional information, if applicable		text box		
1.2.3 PPA application particulars	all	Given name		text box		
	B	Active component(s)	• whole blood • red cells • platelets • plasma • granulocytes • other, please specify	drop down (1)		
		ATC code		Link to ATC codes for selection of the ATC code		ATC code: www.whoc c.no/atc_d dd_index/
		Note: Blood components intended for non-transfusion purposes, e.g. for topical use or injection, may not fall in the scope of the legal basis indicated in Modules 1–5.				

	TC	Active component(s)	• adipose
			  • adipose cells
			  • adipose tissue
			• cardiac
				drop down (1), sub-check box (1–n) tabular format (1–∞ elements)		

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			• cardiac cells • cardiac tissue • cardiovascular • valve • vessel • membrane • amniotic • dura mater • fascia lata • fascia rectus • pericardium • other • muscoskeletal • bone • cartilage • ligament • tendon • neuronal • nerve • ocular • conjunctival • corneal • scleral • other • other mature cells • hepatocytes • keratinocytes • mononuclear cells (mnc) • T cells • pancreas				

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			• pancreatic islet cells • pancreatic tissue • parathyroid • reproductive • ovarian tissue • testicular tissue • skin • dermis • skin • umbilical cord tissue • other, please specify				
		EUTC code		Link to EU coding platform for selection of the EUTC code			EU coding platform: https://webgate.ec.europa.eu/eucoding/reports/eugcproduct/index.xhtml
	HPC	Active component(s)	• hematopoietic progenitor cells • bone marrow • cord blood • peripheral blood • other, please specify	drop down (1)			
		EUTC code		Link to EU coding platform for selection of the EUTC code			EU coding platform: https://webgate.ec.europa.eu/e

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
							ucoding/reports/eugcproduct/index.xhtml

	MAR	Active component(s)	• reproductive
			  • oocytes
			  • sperm
			  • embryos
				drop down (1), sub-check box (1–n)	tabular format (1–∞ elements)		

		EUTC code		Link to EU coding platform for selection of the EUTC code			EU coding platform: https://webgate.ec.europa.eu/eucoding/reports/eugcproduct/index.xhtml
	all	Additional information (e.g. further specification of active component), if applicable		text box			
	all	Origin of the active component for therapy	N/A	N/A			
	B, TC, HPC		• allogeneic • autologous	check box (1–n)			
	TC		• living donor • deceased heart-beating donor (donor after brain death (DBD)) • deceased non-heart beating donor (donor after circulatory death (DCD))	check box (1–n)			
	MAR		• non-partner gametes	check box (1–n)			

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			• partner gametes • donated embryos				
	B, TC, HPC	Qualitative and quantitative composition Provide a description of the qualitative and/or quantitative composition of the active component(s) and excipients, and residues in the final preparation.	N/A	N/A			
	B, TC, HPC	Qualitative description		text box			
	B, TC, HPC	Quantitative description	N/A	N/A			
		Active component(s)/constituent(s) Note: Active constituent(s) of the active component(s), e.g. hemoglobin in red cells, should be mentioned.	Name	text box	tabular format (0–∞ elements) (template is provided in Table 11)		
			Quantity	number/range			
			Unit	text box			
		Excipients Note: Certain substances used in processing, e.g. antibiotics, anticoagulant, or cryoprotectant, should be mentioned.	Name	text box			
			Quantity	number/range			
			Unit	text box			
		Residues Note: Residues of substances and cells, e.g. red cells in platelet concentrate, or pathogen reduction chemical, should be mentioned.	Name	text box			
			Quantity	number/range			
			Unit	text box			

Table 11. Template for quantitative description.

	Name	Quantity	Unit
Active component(s)/constituent(s)[a]	*enter text*	*enter text*	*enter text*

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
		Excipients[b]	…	…	…	
			enter text	*enter text*	*enter text*	
			…	…	…	
		Residues[c]	*enter text*	*enter text*	*enter text*	
			…	…	…	
		[a]Active constituent(s) of the active component(s), e.g. hemoglobin in red cells, should be mentioned. [b]Certain substances used in processing, e.g. antibiotics, anticoagulant, or cryoprotectant, should be mentioned. [c]Residues of substances and cells, e.g. red cells in platelet concentrate, or pathogen reduction chemical, should be mentioned.				
	B, TC, HPC	Additional information, if applicable		text box		
	all	Preparation characteristics	• Plasma, fresh frozen • Plasma, fresh frozen, pathogen-reduced • Cryoprecipitate • Cryoprecipitate, pathogen-reduced • Plasma, fresh frozen, cryoprecipitate-depleted • Plasma, other	drop down (0–1) (example elements for plasma) (elements available for selection depend on the selected category of BTC (Annex 3)		
		Additional information, if applicable		text box		
	all	Summary information about processing For overview purposes only, provide a summary of the most characteristics processing steps in keywords to define the final preparation. For providing more detailed information on the processing steps see section 3.3 of Module 3.	N/A	N/A		

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
	B		• whole blood collection • apheresis • filtration of blood components • filtration of whole blood • washing • freezing • cryopreservation • lyophilisation • pathogen-reduction • please specify • in additive solution • pooling • irradiation • other, please specify	check box (0–n)		
		If pooled, provide the number of pooled units		text box		

	TC		• physical processing (e.g. treatment with heat, treatment with ionising radiation)
			  • please specify
			• chemical processing
			  • please specify
			• biochemical/biologic processing
			  • please specify
			• sterilisation
			  • please specify
			• other, please specify
				check box (0–n)		

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference

			• avital tissue, preserved in a matrix
			• storage in a solution/medium
			  • please specify
			• addition of preservatives
			  • please specify
			• freeze-drying
			• cryopreservation
			• storage above liquid nitrogen
			• warm storage
			• other, please specify
				check box (0–n)		

	HPC		• additional donor plasma collection • volume reduction • plasma reduction • MNC enrichment • RBC depletion • T-cell depletion • B-cell depletion • CD34+ cell enrichment • CD133+ cell enrichment • cryopreservation • other, please specify	check box (0–n)		
	MAR		• cryopreservation of gametes for later IUI or IVF/ICSI • cryopreservation of embryos for later embryo transfer (ET)	check box (0–n)		D6.1

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
			• cryopreservation of reproductive cells for fertility preservation • cryopreservation of reproductive tissues for fertility preservation • oocyte biopsy • embryo biopsy • other, please specify			
	B	Form for clinical application	• suspension (cellular preparations) • solution for infusion (plasma)	drop down (1)		
	TC	Form for clinical application	• solid • semisolid (e.g. gel, paste) • liquid/suspension • intact tissue (e.g. heart, cornea)	drop down (1)		
	HPC	Form for clinical application	• suspension	drop down (1)		
	TC	Description of form for clinical application	N/A	N/A		
		Shape of tissue (e.g. cube, strip, block)		text box		
		Structure of tissue (e.g. granules, bone cement, demineralized/mineralized bone matrix, powder)		text box		
	B, TC, HPC	Additional information, if applicable		text box		
	all	Clinical particulars	N/A	N/A		
	all	Clinical indication(s)		text box (tabular format (1–∞ elements))		
		ICD code		Link to ICD Coding Tool for selection (tabular format (1–∞ elements))		https://icd.who.int/en

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
				of the ICD code		
		Additional information, if applicable		text box		
	all	Method and type of application	N/A	N/A		

	B	Method of application	• intravenous infusion
			  • after thawing
			  • after thawing and washing
			  • after reconstitution (lyophilized plasma)
			• other, please specify
				check box (1–n)		

	TC	Method of application	• surgery • laparoscopy • dressing/topical application • other, please specify	check box (1–n)		

	HPC	Method of application	• intravenous infusion
			  • after thawing
			  • after thawing and washing
			• other, please specify
				check box (1–n)		

	TC	Type of transplant	• permanent • temporary • complete replacement • other, please specify	drop down (1)		
	HPC	Type of transplantation	• single application • other, please specify	drop down (1)		
	MAR	Type of application	• partner donation for direct use	check box (1–n)		

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	Category	Description/instruction	Parameter		Data field type		Legal basis	Additional reference
			• partner donation for not direct use • non-partner donation					
	all	Packaging and pack size	N/A		N/A			
	all	Description of primary packaging Note: Primary packaging system refers to all packaging components that are in direct contact with the preparation.			text box			
		Description of secondary packaging Note: Secondary packaging system refers to all packaging components that provide additional protection to the preparation but are not in direct contact with the preparation.			text box			
		Description of other packaging			text box			
	all	Pack size	from___ml to___ml		number, number			
		Additional information (e.g. pack size(s) for paediatric use), if applicable			text box			
	all	Storage period and condition	N/A		N/A			
	all	Shelf life after procurement	Storage period	max. ___	number	tabular format (template is provided in Table 12)		
				• hours • days • weeks • months • years	drop down (1)			
			Storage temperature	min. ___°C	number			
				max. ___°C	number			

	Category	Description/instruction	Parameter		Data field type	Legal basis	Additional reference
			Additional information (e.g. further storage conditions), if applicable		text box		
		Shelf life after processing	Storage period	max. __ days before	number		
				• irradiation • pathogen reduction • other, please specify	drop down (1)		
				max. __ days after	number		
				• irradiation • pathogen reduction • other, please specify	drop down (1)		
			Additional information (further storage conditions), if applicable		text box		
	all	Changed storage conditions	N/A		N/A		
		after opening the container	Storage period	for immediate application	check box		
				max. __ hours	check box, number		
			Storage temperature	min. ___°C	number		
				max. ___°C	number		
			Additional information (e.g. further storage conditions), if applicable		text box		

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	Category	Description/instruction	Parameter		Data field type		Legal basis	Additional reference
		after preparation for application	Storage period	for immediate application	check box			
				max. __ hours after	check box, number			
				• thawing • thawing and washing • reconstitution • other, please specify	drop down (1)			
			Storage temperature	min. ___°C	number			
				max. ___°C	number			
			Additional information (e.g. further storage conditions), if applicable		text box			
		during transport	Storage period	max. __ hours	number			
			Storage temperature	min. ___°C	number			
				max. ___°C	number			
			Additional information (e.g. further storage conditions), if applicable		text box			

Table 12 Template for storage period and condition.

	Storage period	Storage temperature	Additional information (e.g. further storage conditions), if applicable
Shelf life after procurement	max. __ months	min. __ °C max. __ °C	*enter text*

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
		☒ Shelf life after processing Changed storage conditions after opening the container after preparation for application during transport	max. __ days before irradiation max. __ days after irradiation ☐ for immediate application ☐ max. __ hours ☐ for immediate application ☐ max. __ hours after thawing max. __ hours	enter text min. __ °C max. __ °C min. __ °C max. __ °C min. __ °C max. __ °C		
1.2.4 Legal supply	B, TC, HPC	Legal supply:	• subject to prescription • not subject to prescription	drop down (1)		
		Supply through:	• hospital only • pharmacy only • other, please specify	check box (1–n)		
		Additional information, if applicable		text box		
1.2.5 Applicant/PPA holder and contact persons	all TC, HPC (EU TE code only for TC)	Applicant/PPA holder Applicant/PPA holder contact information is prefilled according to the user profile.	Name (of blood/tissue establishment)	(prefilled according to the user profile)		
			EU TE code, if assigned in the EU TE Compendium	(prefilled according to the user profile)		EU Coding Platform: https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml
			Address, postcode, country	(prefilled according to the user profile)		
			Telephone, telefax, e-mail	(prefilled according to the user profile)		

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		Contact person at this address	Title, first name, surname				
		Attach a proof of establishment (e.g. certificate of registration) of the applicant/PPA holder		file box (1) (prefilled according to the "declaration and signature")			
		Attach a proof of payment for relevant fees paid, if relevant		file box (1) (prefilled according to the "declaration and signature")			
		Additional information, if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
	all	Person/company authorised for communication on behalf of the applicant during the procedure	Title, first name, surname		tabular format (1)		
			Company name				
			Address, postcode, country				
			Telephone, telefax, e-mail				
		Attach a letter of authorisation, if appropriate		file box (1) (prefilled according to the "declaration and signature")			
	all	Person/company authorised for communication between the PPA holder and the CAs after authorisation, if different from the contact person during the procedure	Title, first name, surname		tabular format (0–∞ elements)		
			Company name				
			Address, postcode, country				
			Telephone, telefax, e-mail				
		Attach a letter of authorisation, if appropriate		file box (1)			

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
	B	Responsible person for establishment	Title, first name, surname		tabular format (0–∞ elements)	Article 9 of Directive 2002/98/EC	
			Company name				
			Address, postcode, country				
			Telephone, telefax, e-mail				
			Additional information (e.g. information on the specific tasks for which the person is responsible), if applicable	text box			
		Attach a diploma, certificate or other evidence of relevant formal qualification		file box (1)			
		Additional information (e.g. curriculum vitae, diploma), if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
	TC, HPC, MAR	Responsible person for establishment	Title, first name, surname		tabular format (1)	Article 17 of Directive 2004/23/EC	
			Company name				
			Address, postcode, country				
			Telephone, telefax, e-mail				
			Additional information (e.g. information on the specific tasks for which the person is responsible), if applicable	text box			
		Attach a diploma, certificate or other evidence of relevant formal qualification		file box (1)			
		Additional information (e.g. curriculum vitae), if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
	all	Other contact person, please specify	Function (e.g. representative of responsible person)	text box	tabular format (0–∞ elements)		

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			Title, first name, surname				
			Company name				
			Address, postcode, country				
			Telephone, telefax, e-mail				
			Additional information (e.g. information on the specific tasks for which the person is responsible), if applicable	text box			
		Additional information, if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
1.2.6 Processing and testing sites	all	Release site(s)	Name of site		tabular format (0–∞ elements)		
			Address, postcode, country				
			Telephone, telefax, e-mail				
		Attach a copy of manufacturer licence		file box (1)			
		Processing site(s) Description of functions/processing steps performed by each processing site are to be indicated in flow-chart in section 3.3 of Module 3.	Name of site		tabular format (1–∞ elements)		
			Address, postcode, country				
			Telephone, telefax, e-mail				
		Attach a copy of manufacturer licence		file box (1)			
	all	Donor testing laboratories	Name of site		tabular format (1–∞ elements)		
			Address, postcode, country				
			Telephone, telefax, e-mail				
	all	Quality control sites	Name of site		tabular format (1–∞ elements)		
			Address, postcode, country				
			Telephone, telefax, e-mail				
		Attach a copy of manufacturer licence		file box (1)			

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		Additional information, if applicable		text box			
	all	Criteria for donor testing laboratories	N/A	N/A			D7.1 Ch. 2
	all	Name of donor testing laboratory		drop down (values provided in section 1.2.6 Module 1)	tabular format (0–∞ elements) (Example template is provided in Table 13		
	all	Quality system(s) of the laboratory	N/A	N/A			
	B	Laboratory has a well-managed quality system, and meets the quality system standards and specifications for blood establishments as defined in Directive 2005/62/EC		check box		Directive 2005/62/EC	
	TC, HPC, MAR	Laboratory has a well-managed quality system, and meets the quality system standards and specifications for testing laboratory as defined in Directive 2004/23/EC		check box		Directive 2004/23/EC	
	all	Additional information, if applicable		text box			
	all	Standard(s) that the laboratory follows	N/A	N/A			
	B	Laboratory follows the minimum standards as defined in Directive 2002/98/EC		check box		Directive 2002/98/EC	
	TC, HPC, MAR	Laboratory follows the minimum standards as defined in Directive 2004/23/EC		check box		Directive 2004/23/EC	
	all	Additionally, the laboratory follows the following standards (e.g. EN ISO 15189, EN ISO 17025, national standards):		text box		ISO 15189 (Regulation (EU) 2017/746*	

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		Note: Laboratory using in-house assay for BTC donor infectious disease marker testing must be compliant with standard EN ISO 15189 (Regulation (EU) 2017/746)				(*laboratories using in-house tests)	
	all	Accreditation, designation, authorisation or licensing of laboratory	N/A	N/A			
		Name of the accreditation authority:		text box		Directive 2002/98; Directive 2006/17 Annex II 2.1	
		Name of the external accreditation body, if applicable:		text box		Directive 2002/98; Directive 2006/17 Annex II 2.1	
		Table 13. Example template for criteria for donor testing laboratories (blood components). › Laboratory B **Quality system(s) of the laboratory** ☐ Laboratory has a well-managed quality system, and meets the quality system standards and specifications for blood establishments as defined in Directive 2005/62/EC Additional information, if applicable: *enter text* **Standard(s) that the laboratory follows** ☐ Laboratory follows the minimum standards as defined in Directive 2002/98/EC Additionally, the laboratory follows the following standards (e.g. EN ISO 15189, EN ISO 17025, national standards): *enter text*					

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		Accreditation, designation, authorisation or licensing of laboratory Name of the accreditation authority: *enter text* Name of the external accreditation body, if applicable: *enter text*					
1.2.7 Other sites/contact persons	all		Function (e.g. co-distributor)	text box	tabular format (0–∞ elements)		
			Name of site				
			Address, postcode, country				
			Telephone, telefax, e-mail				
		Additional information, if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
1.2.8 Annexed documents	all	If applicable, in this section, provide attachments to the application form and documents not fitting into Modules 2–5.	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

1.3 Accompanying document and labelling

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
	all	Note: If revision of accompanying documents and labelling is proposed (e.g. in case of renewal or change), the proposed changes should be clearly indicated.	N/A	N/A		
1.3.1 Accompanying document	all	Provide accompanying documents		text box		
				file box (download-upload) (1)		

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1.3.2 Labelling	B	Provide labelling documents. Labelling must comply with the requirements set out in Annex III to Directive 2002/98/EC Note: For autologous blood and blood components, labelling must also comply with Article 7 of Directive 2004/33/EC and the additional requirements for autologous donations set out in Annex IV to Directive 2004/33/EC.	N/A	N/A		Directive 2002/98/EC; Directive 2004/33/EC	
	TC, HPC, MAR	Provide labelling documents. Labelling must comply with the requirements set out in Annex IV to Directive 2006/17/EC.	N/A	N/A		Directive 2006/17/EC	
	all	Primary packaging		file box (download-upload) (1)			
	all	Secondary packaging		file box (download-upload) (1)			
1.3.3 Other	all	Additional information, if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

1.4 Experts

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
	all	Provide information about the necessary expertise of the quality, non-clinical, and clinical experts, who draw up the expert reports provided in section 2.3 of Module 2. Curriculum vitae should include name of expert, education and professional experience as evidence for the relevant field of expertise, date and signature.	N/A	N/A		
1.4.1 Quality	all	Provide the quality expert statement		file box (download-upload)		

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
				(example of template is provided in Figure 25)			
		Attach a curriculum vitae of the quality expert		file box (1)			
		Additional information (e.g. diploma), if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

According to his/her respective qualifications the undersigned expert declares hereby to have created the quality expert report.

Quality
Name of the expert: _____ Signature:
Address: _____
_____
_____
_____

Date:

☐ Brief information (curriculum vitae) on the education and professional experience as evidence for the relevant field of expertise is attached.

Figure 25. Example of template for quality expert statement. Adapted from NTA, Vol. 2B-CTD[6]

1.4.2 Non-clinical	all	Provide the non-clinical expert statement		file box (download-upload)			
		Attach a curriculum vitae of the non-clinical expert		file box (1)			
		Additional information (e.g. diploma), if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			Additional information, if applicable	text box			
1.4.3 Clinical	all	Provide the clinical expert statement		file box (download-upload)			
		Attach a curriculum vitae of the clinical expert		file box (1)			
		Additional information (e.g. diploma), if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

1.5 Vigilance

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
1.5.1 Vigilance system	B	Provide description of vigilance system, as laid down in Directive 2002/98/EC		text box		Directive 2002/98/EC	
	TC, HPC, MAR	Provide description of vigilance system, as laid down in Directive 2006/86/EC		text box		Directive 2006/86/EC	
	all	Additional information, if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
1.5.2 Risk-management system	all	Provide description of risk-management system		text box			EuroGTPII Guide
		Additional information, if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

1.6 Additional information

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
	all	If applicable, provide any additional administrative, regional or national information (e.g. nationally required additional information, ethics committee approval, a statement that clinical investigations carried out outside of the European Union meet the ethical requirements) in this section.		text box			
			Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

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Module 2 – Overview and summaries

2.1 General information

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
	all	A general introduction to the BTC is provided in this section. Further information on BTC is located in section 1.2.3 of Module 1.	N/A	N/A		
	all	Given name		(prefilled according to section 1.2.3 of Module 1, cannot be changed in this section)		
	B	Active component(s)		(prefilled according to section 1.2.3 of Module 1, cannot be changed in this section)		
		ATC code				
	TC, HPC, MAR	Active component(s)		(prefilled according to section 1.2.3 of Module 1, cannot be changed in this section)		
		EUTC code				
	all	Clinical indication(s)		(prefilled according to section 1.2.3 of Module 1, cannot be changed in this section)		
		ICD code				
		Additional information, if applicable				
	all	Method of application		(prefilled according to section 1.2.3 of Module 1, cannot be changed in this section)		

2.2 Risk analysis

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
2.2.1 Risk analysis	all	The risk analysis is performed to profile and assess risks associated with the clinical use of BTC and resulted from all aspects of preparation process and clinical application of BTC. The risk analysis serves for	N/A	N/A		EuroGTP II

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		identification of the extent of non-clinical and clinical data included to support the PPA. It can be used as a basis for the risk management plan located in section 1.5.2 of Module 1.					
	all	Risk profiling Provide all available information on relevant risks and risk factors contributing to each risk, in order to obtain a risk profile associated with BTC in the given therapeutic context. Risk mitigation strategies applied, should be briefly specified. All non-clinical and clinical evaluations, and the possible risks and adverse reactions anticipated based on prior experiences should be considered. Other relevant data such as literature, data generated by other blood/tissue establishments, or clinical use of similar BTC, may also be considered. Definition: Risks include any relevant risks to the recipient or offspring. Risks associated with BTC may include unexpected immunogenicity, implant failure/engraftment failure/pregnancy loss, disease transmission, toxicity/carcinogenicity, and other risks. Definition: Risk factors refer to characteristics that contribute to particular	Risk factor	text box	tabular format (0–∞ elements) (template is provided in Table 14)		
			Risk	text box			
			Risk factor/risk relationship	text box			
			Evidence	text box			
			Risk mitigation	text box			
			Additional information, if applicable	text box			

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		risk(s) after clinical application of BTC. Risk factors associated with BTC may include the origin, donation/procurement, processing, storage, and clinical application procedures of BTC.					

Table 14. Template for risk profiling.

Risk factor	Risk	Risk factor/risk relationship	Evidence	Risk mitigation	Additional information, if applicable
e.g. impurities	*e.g. toxicity/ carcinogenicity*	*e.g. Impurities might contribute to tumor development*	*e.g. Investigation XYZ (see Module 5)*	*e.g. Control of impurities addressed in quality testing prior release (see section 3.4 of Module 3)*	
…	…	…	…	…	

B	Assess the risks associated with BTC or its preparation process using the Blood risk assessment tool.		Link: tool.goodtissuepractices.site		EuroGTP II Interactive Assessment Tool
TC, HPC, MAR	Assess the risks associated with BTC or its preparation process using the Tissues and cells risk assessment tool.		Link: tool.goodtissuepractices.site		EuroGTP II Interactive Assessment Tool
all	Upload the risk assessment report as received from the risk assessment tool		file box (1–∞)		

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
	all	Discussion of the outcome of the risk analysis Discuss the outcome of the risk analysis including the methodology followed (e.g. risk assessment tool), relevant risk factors, risk consequences for recipient or offspring, and risk mitigation strategies applied. Evaluate the overall risk of BTC in relation to its benefits. After sufficiently mitigated risks and hence a positive benefit-risk profile justifying the use of BTC in a clinical setting, the remaining level of risk should determine the extent of collecting of post-authorisation clinical data.		text box		D8.3 Ch. 2 EuroGTP II
		Alternatively, the discussion of the outcome of the risk analysis can be uploaded		file box (1–∞)		
	all	Provide the estimate of the level of remaining risk associated with the clinical use (outcome of the risk assessment):	• high • moderate • low • negligible	drop down (1) • Selection of “high” or “moderate” activates “SARE reporting”, “CFUpP”, “CIP” (see below) • Selection of “low” activates “ SARE reporting”, “CFUpP”, (“CIP” greyed out, but still selectable) (see below) • Selection of “negligible” activates “ SARE reporting”, (“CFUpP” and		D8.3 Ch. 2

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	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
				"CIP" greyed out, but still selectable) (see below)		
2.2.2 Plan for collecting post-authorisation data	all	Based on the level of remaining risk associated with the clinical use, following information should be provided as plan for collecting post-authorisation clinical data:	N/A	N/A		D8.3 Ch. 2
	B	Vigilance reporting (serious adverse reactions and events (SAR/SAE)) according to Directive 2002/98/EC.		check box	Directive 2002/98/EC	Common Approach document;
	TC, HPC, MAR	Vigilance reporting (serious adverse reactions and events (SAR/SAE)) according to Directive 2006/86/EC.		check box	Directive 2006/86/EC	
	all	Clinical follow-up plan (CFUpP)		check box D8.4 form (to be filled in within the platform, or downloaded, filled in, and uploaded)		D8.3 Ch. 5 D8.4
		Number of BTC applications/recipients planned to be included in the clinical follow-up		number		
		Duration of clinical follow-up		number		
	all	Clinical investigation plan (CIP)		check box D8.4 form (to be filled in within the platform, or downloaded, filled in, and uploaded)		D8.3 Ch. 6, Ch. 7 D8.4

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
		Number of BTC applications/recipients planned to be included in the clinical investigation		number		
		Duration of clinical investigation		number		
		Multicenter investigation	• yes • no	check box (1)		
		List of centers and countries involved in the clinical investigation, if applicable		text box / tabular format (0–∞ elements)		
		Control treatment used, if applicable		text box		
		Independent Ethics Committee decisions/opinions		file box (1–∞)		
		Agreement between BE/TE and clinicians/institutions		file box (1–∞)		
		CV(s) of Principal Investigator(s)		file box (1–∞)		
	all	Note: The results of the clinical follow-up and/or investigation will be provided in Module 5 and discussed in section 2.3.3 of Module 2.	N/A	N/A		

2.3 Overview and summaries

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
2.3.1 Quality	all	Emphasise key critical parameters and issues related to quality aspects. Any important limitations of the available data should be addressed. In cases where the relevant guidelines were not followed, justification should be provided. The quality summary follows the scope and outline of the corresponding data provided in Module 3.		text box		

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		Alternatively, the quality expert report can be uploaded		file box (1)			
	all	Appendices to the quality expert report	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
2.3.2 Non-clinical	all (full application)	Provide a summary (detailed summary of the outcomes) and overview (critical analysis, discussion and interpretation of the outcomes) of the non-clinical data presented in Module 4. Any important limitations of the available data should be addressed. In cases where the relevant guidelines were not followed, justification should be provided.		text box			
		Alternatively, the non-clinical expert report can be uploaded		file box (1)			
	all (bibliographic application)	Provide a summary (detailed summary) and overview (critical analysis, discussion and interpretation) of the non-clinical grounds and evidence used to demonstrate a well-established use.		text box			
		Alternatively, the non-clinical expert report can be uploaded		file box (1)			
	all	Appendices to the non-clinical expert report	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
2.3.3 Clinical	all	Provide a summary (detailed summary of the outcomes) and overview (critical		text box			

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
	(full application)	analysis, discussion and interpretation of the outcomes) of the clinical data presented in Module 5 (including an evaluation of benefits and risks). Any important limitations of the available data should be addressed. In cases where the relevant guidelines were not followed, justification should be provided.					
		Alternatively, the clinical expert report can be uploaded		file box (1)			
	all (bibliographic application)	Provide a summary (detailed summary) and overview (critical analysis, discussion and interpretation) of the clinical grounds and evidence used to demonstrate a well-established use. A well-established use should be demonstrated with regard to safety and efficacy.		text box			
		Alternatively, the clinical expert report can be uploaded		file box (1)			
	all	Appendices to the clinical expert report (e.g. summary of clinical efficacy, summary of clinical safety).	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

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Module 3 – Quality

3.1 General information

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
	all	A general introduction to the BTC is provided in this section. Further information on BTC is located in section 1.2.3 of Module 1.	N/A	N/A		
	all	Given name		(prefilled according to section 1.2.3 of Module 1, cannot be changed in this section)		
	B, TC, HPC	Qualitative and quantitative composition		(prefilled according to section 1.2.3 of Module 1, cannot be changed in this section)		
	B, TC, HPC	Form for clinical application		(prefilled according to section 1.2.3 of Module 1, cannot be changed in this section)		

3.2 Donor selection and testing

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
3.2.1 Donor selection criteria	B	Confirm the compliance with the specific quality and safety requirements for donation, procurement and testing, set out in Directive 2004/33/EC and Directive 2002/98/EC.		check box (1)	Directive 2004/33/EC; Directive 2002/98/EC	
		Confirm the compliance with any additional national requirements that may apply, please specify		check box (0–∞)		
				text box (0–∞)		
	TC, HPC, MAR	Confirm the compliance with the specific quality and safety requirements for donation, procurement and testing, set out		check box (1)	Directive 2006/17/EC;	

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		in Directive 2006/17/EC and Directive 2004/23/EC.				Directive 2004/23/EC	
		Confirm the compliance with any additional national requirements that may apply, please specify		check box (0–∞)			
				text box (0–∞)			
	MAR	Note: Donor selection criteria apply to non-partner donation and testing applies to non-partner donation and partner donation (not direct use), as laid down in Annex III to Directive 2006/17/EC.	N/A	N/A		Annex III to Directive 2006/17/EC	
	all	Attach a description of donor selection (e.g. donor ID, donor eligibility criteria, anamnesis)		file box (0–∞)			
	all	Questionnaires Questionnaires serve for assessment of the donor's health and medical history for further identification of persons whose donation could cause a health risk to recipients or to donors themselves.	N/A	N/A			
		Attach a donor questionnaire		file box (0–∞))			
		Attach a donor anamnesis questionnaire, if applicable		file box (0–∞))			
		Additional attachments (e.g. statement of voluntary unpaid nature of donation, donor self-deferral form, information material for donors), if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
	B, TC, MAR	Additional information, if applicable		text box			

	Category	Description/instruction	Parameter		Data field type		Legal basis	Additional reference
	HPC	Additional information (e.g. preparative conditioning regimen for peripheral blood stem cell donors/recipients), if applicable			text box			
3.2.2 Donor/donation testing	all	Testing before donation Provide information on test strategies and methods used. Testing of the donor blood before donation includes e.g. determination of ABO blood group, blood cell count.			file box (download-upload) (1)			
	all	Testing for infectious disease Confirm the conduction of the following donor/donation testing	N/A		N/A			
	B	Note: As minimum requirement, all blood donors/donations must be tested for HIV 1/2 (Anti-HIV-1/2), Hepatitis B (HBsAg), Hepatitis C (Anti-HCV-Ab) in conformity with Annex IV to Directive 2002/98/EC. Additional national requirements may apply.	Parameter	• Anti-HIV-1/2 • HBsAg • Anti-HCV-Ab		check box (n) tabular format (n–∞ elements) (template is provided in Table 15)	Annex IV to Directive 2002/98/EC	D7.1 Ch. 3
			Acceptance criteria	negative				
			Frequency of control	100%				
			Additional information, if applicable		text box			
	TC, HPC	Note: As minimum requirement, all tissue and cell donors must be tested for HIV 1/2 (Anti-HIV-1/2), Hepatitis B (HBsAg, Anti-HBc), Hepatitis C (Anti-HCV-Ab), *Treponema pallidum* in conformity with Annex II to	Parameter	• Anti-HIV-1/2 • HBsAg • Anti-HBc Anti-HCV-Ab		check box (n) tabular format (n–∞ elements)	Annex II to Directive 2006/17/EC	D7.1 Ch. 3

	Category	Description/instruction	Parameter		Data field type		Legal basis	Additional reference
		Directive 2006/17/EC. Additional national requirements may apply.		• *Treponema pallidum*		(example template is provided in Table 15, to be adapted according to values listed in Parameter)		
			Acceptance criteria	negative				
			Frequency of control	100%				
			Additional information, if applicable	text box				
	MAR	Note: As minimum requirement, all reproductive cell donors must be tested for HIV 1/2 (Anti-HIV-1/2), Hepatitis B (HBsAg, Anti-HBc), Hepatitis C (Anti-HCV-Ab), *Treponema pallidum* (non-partner donors), Chlamydia (non-partner sperm donors) in conformity with Annex III to Directive 2006/17/EC. Additional national requirements apply.	Parameter	• Anti-HIV-1/2 • HBsAg • Anti-HBc • Anti-HCV-Ab • *Treponema pallidum*[a] ([a]non-partner donors) • Chlamydia[b] ([b]non-partner sperm donors)		check box (n) tabular format (n–∞ elements) (example template is provided in Table 14, to be adapted according to values listed in Parameter)	Annex III to Directive 2006/17/EC	D7.1 Ch. 3
			Acceptance criteria	negative				

<table>
<tr><th></th><th>Category</th><th>Description/instruction</th><th colspan="2">Parameter</th><th colspan="2">Data field type</th><th>Legal basis</th><th>Additional reference</th></tr>
<tr><td></td><td></td><td></td><td>Frequency of control</td><td>100%</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>Additional information, if applicable</td><td></td><td>text box</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td colspan="7">Table 15. Template for minimum requirements for blood donor/donation testing.
<table>
<tr><th></th><th>Parameter</th><th>Acceptance criteria</th><th>Frequency of control</th><th>Additional information, if applicable</th></tr>
<tr><td>☐</td><td>Anti-HIV-1/2</td><td>negative</td><td>100%</td><td></td></tr>
<tr><td>☐</td><td>HBsAg</td><td>negative</td><td>100%</td><td></td></tr>
<tr><td>☐</td><td>Anti-HCV-Ab</td><td>negative</td><td>100%</td><td></td></tr>
<tr><td>☐</td><td>…</td><td>…</td><td>…</td><td></td></tr>
</table></td></tr>
<tr><td></td><td>all</td><td>Test kit/in-house test</td><td>Parameter</td><td>drop down

(values provided in Table 15)</td><td rowspan="6">tabular format (0–∞ elements)

(template is provided in Table 16Table 16)</td><td rowspan="6"></td><td rowspan="6"></td></tr>
<tr><td></td><td></td><td>Manufacturer</td><td>text box</td></tr>
<tr><td></td><td></td><td>Name of test kit/in-house test</td><td>text box</td></tr>
<tr><td></td><td></td><td>Art. no./cat. ref. no.</td><td>text box</td></tr>
<tr><td></td><td></td><td>CE-marked kit / in-house test</td><td>drop down</td></tr>
<tr><td></td><td></td><td>Additional information (e.g. package leaflet), if applicable</td><td>text box
file box</td></tr>
<tr><td></td><td></td><td colspan="7">Table 16. Template for test kits and in-house tests.</td></tr>
</table>

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<table>
<tr><th></th><th>Category</th><th>Description/instruction</th><th>Parameter</th><th>Data field type</th><th>Legal basis</th><th>Additional reference</th></tr>
<tr><td></td><td></td><td colspan="5">
<table>
<tr><th>Parameter</th><th>Manufacturer</th><th>Name of test kit/in-house test</th><th>Art. no./cat. ref. no.</th><th>CE-marked kit / in-house test</th><th>Additional information (e.g. package leaflet), if applicable</th></tr>
<tr><td>Anti-HCV-Ab</td><td>enter text</td><td>enter text</td><td>enter text</td><td>CE-marked kit</td><td>enter text
descriptive file name | upload file</td></tr>
<tr><td>…</td><td>…</td><td>…</td><td></td><td>…</td><td>…</td></tr>
</table>
</td></tr>
<tr><td></td><td>all</td><td>Donor/donation testing procedure

Describe procedures used for donor/donation testing. If appropriate, validation information should be provided to demonstrate that the procedures are suitable for their intended purpose.</td><td>Parameter</td><td>drop down

(values provided in Table 15)</td><td>tabular format (0–∞ elements)

(template is provided in Table 17)</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>Name of test kit/in-house test</td><td>drop down

(values provided in Table 16)</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>Testing laboratory</td><td>drop down

(values provided in section 1.2.6 of Module 1)</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>Procedure</td><td>text box</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>Validation protocol, if relevant

Note: e.g. for use with post-mortem samples</td><td>file box</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>For NAT only, additional information</td><td>text box</td><td></td><td></td><td></td></tr>
</table>

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<table>
<tr><th></th><th>Category</th><th>Description/instruction</th><th>Parameter</th><th>Data field type</th><th>Legal basis</th><th>Additional reference</th></tr>
<tr><td></td><td></td><td>

Table 17. Template for donor/donation testing procedure.

<table>
<tr><th>Parameter</th><th>Name of test kit/in-house test</th><th>Testing laboratory</th><th>Procedure</th><th>Validation protocol[a], if relevant</th><th>For NAT only, additional information</th></tr>
<tr><td>Anti-HIV-1/2</td><td>- select -</td><td>- select -</td><td>other, please specify</td><td>descriptive file name | upload file</td><td>Max. pool size: enter text
Sensitivity (95% CI): enter text
Sensitivity of a single donation in the pool: enter text
Sample preparation: enter text
Analysis device: enter text</td></tr>
<tr><td>…</td><td>…</td><td>…</td><td>…</td><td>…</td><td>…</td></tr>
</table>

[a]e.g. for use with post-mortem samples

</td><td></td><td></td><td></td></tr>
<tr><td></td><td>all</td><td>Archive samples

Definition: Archive samples (samples of donor blood) are kept for additional testing for infectious diseases</td><td>Number of samples
Volume in each sample
Storage period
Storage temperature
Additional information (e.g. further storage conditions), if applicable</td><td>number
number
text box
text box
text box</td><td>tabular format

(template provided in Table 18)</td><td></td><td></td></tr>
<tr><td></td><td></td><td colspan="5">

Table 18. Template for archive blood samples.

<table>
<tr><th>Storage period</th><th>Storage temperature</th><th>Additional information (e.g. further storage conditions), if applicable</th></tr>
<tr><td>min. __ years</td><td>min. ___°C max. ___°C</td><td>enter text</td></tr>
</table>

</td></tr>
</table>

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
3.2.3 Materials	all	Provide a list of materials, reagents and excipients involved in the procedure of donation, procurement, or testing. Suitability of materials for the intended use should be clearly specified and evaluated.	Name	text box	tabular format (0–∞ elements)		
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			Description of the use in the process	text box			
			Additional information (e.g. reference document), if applicable	text box file box			
3.2.4 Equipment	all	Provide a list of equipment, instruments and devices, involved in the procedure of donation, procurement, or testing. Suitability of equipment for the intended use should be clearly specified and evaluated.	Type of equipment (e.g. centrifuge)	text box	tabular format (0–∞ elements)		
			Name, model	text box			
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			Description of the use in the process	text box			
			Additional information (e.g. reference document), if applicable	text box file box			

3.3 Processing

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
3.3.1 Processing and in-process controls	all	Processing in open/closed systems	Open-system procurement	check box			D7.1 Ch. 6.2
			Open-system processing	check box			
	all	Flow diagram	Process	text box	tabular format (0–∞ elements)		Pathogen reduction: D7.1 Ch. 4;
			In-process controls	text box			
			Processing time	text box			

<table>
<tr><th></th><th>Category</th><th>Description/instruction</th><th>Parameter</th><th colspan="2">Data field type</th><th>Legal basis</th><th>Additional reference</th></tr>
<tr><td rowspan="3"></td><td rowspan="3"></td><td rowspan="2">Describe the successive steps of the entire preparation process, typically from donation up to the storage after release and shipping conditions of the final BTC. For each process step, all materials added or eliminated, intermediates, reagents and equipment used, and appropriate process parameters (e.g. time, temperature, pH) should be provided.

Identify critical steps (e.g. pathogen reduction, sterilisation) and steps in which in-process controls are carried out. Strategies for control of critical steps when any should be briefly provided.</td><td>Processing/testing site for process</td><td>drop down

(values provided in section 1.2.6 of Module 1)</td><td>(template is provided in Table 19)</td><td rowspan="2"></td><td rowspan="2">Sterilisation: D7.1 Ch. 5</td></tr>
<tr><td>Additional information (e.g. validation protocol, materials, equipment), if applicable</td><td>text box
file box</td><td></td></tr>
<tr><td colspan="6">Table 192. Template for flow diagram.
<table>
<tr><th>Process</th><th>In-process controls</th><th>Processing time</th><th>Processing/testing site for process</th><th>Additional information (e.g. validation protocol, materials, equipment), if applicable</th></tr>
<tr><td>enter text</td><td>enter text</td><td>enter text</td><td>- select -</td><td>enter text
descriptive file name upload file</td></tr>
</table></td></tr>
<tr><td></td><td>Alternatively, the flow chart can be uploaded</td><td></td><td>file box (1)</td><td></td><td></td><td></td></tr>
<tr><td></td><td>all</td><td>Narrative of processing

If relevant, provide a narrative of the processing, including identification of critical steps, in-process controls, materials, equipment and operating conditions.</td><td></td><td>text box</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td>Alternatively, the narrative of processing and/or SOP can be uploaded</td><td></td><td>file box (1–∞)</td><td></td><td></td><td></td></tr>
</table>

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
	HPC	Archive samples Definition: Archive samples of HPC component are kept for additional testing as necessary. The archive samples are to be processed and stored under the same conditions as the HPC component.	Number of samples	number			
			Volume in each sample	number			
			Storage period	text box	tabular format (template is provided in Table 20)		
			Storage temperature	text box			
			Additional information (e.g. further storage conditions), if applicable	text box			

Table 20. Template for test samples.

Storage period	Storage temperature	Additional information (e.g. further storage conditions), if applicable
min. __ weeks	min. ___°C max. ___°C	*enter text*

3.3.2 Materials	all	Provide a list of materials, reagents and excipients involved in the processing. Suitability of materials for the intended use should be clearly specified and evaluated.	Name	text box	tabular format (0–∞ elements)		
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			Description of the use in the process	text box			
			Additional information (e.g. reference document), if applicable	text box file box			
3.3.3 Equipment	all	Provide a list of equipment, instruments and devices, involved in the processing. Suitability of equipment for the intended use should be clearly specified and evaluated.	Type of equipment (e.g. centrifuge)	text box	tabular format (0–∞ elements)		
			Name, model	text box			
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			Description of the use in the process	text box			

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			Additional information (e.g. reference document), if applicable	text box file box			
3.3.4 Facilities	all	If relevant, provide information on design features of the facilities (e.g. area classifications) to prevent contamination or cross-contamination of areas and equipment in preparation process. Consider specific requirements for facilities relevant if preparation is performed in an open system/aseptically without further sterilisation.		text box file box (1)			
		Additional information (e.g. facility layout, floor plan), if applicable	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

3.4 Quality control

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
3.4.1 Quality attributes for quality control prior to release	all	Provide criteria for quality controls prior to release. Additional quality controls may apply.	N/A	(example template is provided in Table 21)		
		Select the most appropriate template		drop down (values provided depend on the selected category of BTCM)		
		Table 21. Example template for quality controls prior to release for organ-cultured corneal donor tissue for (deep) anterior lamellar keratoplasty (ALK/DALK).				

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference

	Quality attribute	Acceptance criteria		Frequency of control	Time of sampling	Additional information, if applicable
Identity						
☐	Size of graft (diameter of clear central area of cornea)	*7,50*	mm	*100%*	*after processing*	*Stroma is clear and without scars within a 7,50 mm diameter zone*
☐	Appearance and description (stromal opacities)	*Absence of stromal opacities*		*100%*	*after processing*	*enter text*
☐	Morphology and structural integrity of the cornea layers, if applicable	*≥ 2 000*	cells/mm²	*100%*	*after processing*	*Endothelial cell density measurement by microscopy; ≥ 2 000 cells/mm² at the end of organ-culture storage, or ≥ 2 200 cells/mm² if only determined before organ culture*
☐	*enter text*	*enter text*	*enter text*	*100%*	*enter text*	*enter text*
Functionality						
☐	Functional competence (endothelial characteristics)	*Viable, functioning endothelium*		*100%*	*after processing*	*Viable, functioning endothelium may be required for DALK if surgeon needs to switch to penetrating keratoplasty (PK) because anterior chamber penetrated*
☐	*enter text*	*enter text*	*enter text*	*100%*	*enter text*	*enter text*
Purity and impurities						
☐	*enter text*	*enter text*	*enter text*	*100%*	*enter text*	*enter text*
Microbial growth						
☐	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*		*100%*	*prior to release*	*Not to be used if the organ-culture medium is turbid or becoming yellow, or if samples of medium are culture-positive for bacteria or fungi*
☐	*enter text*	*enter text*	*enter text*	*100%*	*enter text*	*enter text*
Infectious disease markers						
☐	*enter text*	*enter text*	*enter text*	*100%*	*enter text*	*enter text*
Other						
☐	*enter text*	*enter text*	*enter text*	*100%*	*enter text*	*enter text*

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<table>
<tr><th></th><th>Category</th><th>Description/instruction</th><th>Parameter</th><th colspan="2">Data field type</th><th>Legal basis</th><th>Additional reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td colspan="2"></td><td></td><td></td></tr>
<tr><td rowspan="6">3.4.2 Quality control procedures</td><td rowspan="6">all</td><td rowspan="6">Quality control procedures

Describe procedures used for quality controls prior to release. If appropriate, validation information should be provided to demonstrate that the procedures are suitable for their intended purpose.</td><td>Quality attribute</td><td>drop down

(values provided in Table 21)</td><td rowspan="6">tabular format (0–∞ elements)

(template is provided in Table 22)</td><td rowspan="6"></td><td rowspan="6"></td></tr>
<tr><td>Testing laboratory</td><td>drop down

(values provided in section 1.2.6 of Module 1)</td></tr>
<tr><td>Procedure</td><td>text box</td></tr>
<tr><td>Validation protocol, if relevant</td><td>file box</td></tr>
<tr><td>Additional information (e.g. package leaflet), if applicable</td><td>text box</td></tr>
<tr><td>file box</td></tr>
<tr><td colspan="8">Table 22. Template for quality control procedure.
<table>
<tr><th>Quality attribute</th><th>Testing laboratory</th><th>Procedure</th><th>Validation protocol, if relevant</th><th>Additional information (e.g. package leaflet), if applicable</th></tr>
<tr><td>- select -</td><td>- select -</td><td>enter text</td><td>descriptive file name upload file</td><td>enter text
descriptive file name upload file</td></tr>
<tr><td>…</td><td>…</td><td>…</td><td>…</td><td>…</td></tr>
</table>
</td></tr>
<tr><td>3.4.3 Materials</td><td>all</td><td>Provide a list of materials, reagents and excipients involved in quality controls.</td><td>Name</td><td>text box</td><td>tabular format (0–∞ elements)</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>Art. no./cat. ref. no.</td><td>text box</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td>Manufacturer</td><td>text box</td><td></td><td></td><td></td></tr>
</table>

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		Suitability of materials for the intended use should be clearly specified and evaluated.	Description of the use in the process	text box			
			Additional information (e.g. reference document), if applicable	text box file box			
3.4.4 Equipment	all	Provide a list of equipment, instruments and devices, involved in quality controls. Suitability of equipment for the intended use should be clearly specified and evaluated.	Type of equipment (e.g. centrifuge)	text box	tabular format (0–∞ elements)		
			Name, model	text box			
			Art./cat. no	text box			
			Manufacturer	text box			
			Description of the use in the process	text box			
			Additional information (e.g. reference document), if applicable	text box file box			

3.5 Packaging system

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
3.5.1 Description of packaging system	all	Note: Packaging system refers to all primary and secondary packaging components that protect the preparation.	N/A	N/A			
	all	Primary packaging Note: Primary packaging system refers to all packaging components that are in direct contact with the preparation.	Name	text box	tabular format (1–∞ elements)		
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			CE-marking	check box			
			Materials Note: Materials refer to the chemical compounds used to	text box			

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			manufacture single components of a packaging system.				
			Additional information (e.g. reference document, diagram of packaging system), if applicable	text box file box			
	all	Secondary packaging Note: Secondary packaging system refers to all packaging components that provide additional protection to the preparation but are not in direct contact with the preparation.	Name	text box	tabular format (1–∞ elements)		
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			CE-marking	check box			
			Materials Note: Materials refer to the chemical compounds used to manufacture single components of a packaging system.	text box			
			Additional information (e.g. reference document), if applicable	text box file box			
	all	Other packaging For other (non-functional) packaging system(s), provide a brief description.		text box			
	all	Labelling on the primary packaging	N/A	N/A			
		Primary package label	Name	text box	tabular format (1–∞ elements)		
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			Materials	text box			
			Additional information (e.g. expert report on migration behaviour and toxicological	text box file box			

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			safety, reference document), if applicable				
		Printing ink	Name	text box	tabular format (1–∞ elements)		
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			Additional information (e.g. expert report on migration behaviour and toxicological safety, reference document), if applicable	text box			
				file box			
		Adhesive	Name	text box	tabular format (1–∞ elements)		
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			Additional information (e.g. expert report on migration behaviour and toxicological safety, reference document), if applicable	text box			
				file box			
3.5.2 Summary and conclusion of packaging system	all	Discuss the suitability of the packaging system with respect to, e.g. choice of materials, protection from damage, temperature control, compatibility of the materials with the preparation including sorption to container and leaching, safety of materials, or performance.		text box			
		Alternatively, the summary and conclusion of packaging system can be uploaded		file box			

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3.6 Validation and stability

	Category	Description/instruction	Parameter	Data field type	Legal basis	Additional reference
	all	Validation procedure (stability testing) is used to determine the quality of BTC achieved by the processing and testing laid down in this application. The procedure provides evidence on how the quality of BTC varies with time under influence of environmental factors (e.g. temperature). Validation should be conducted to demonstrate worst-case scenario. Data are used to specify shelf life and storage conditions.	N/A	N/A		D6.1
3.6.1 Quality attributes for validation	all	Quality attributes for validation Provide quality attributes known to be critical for the stability.	N/A	(example template is provided in Table 23)		D6.1
		Select the most appropriate template		drop down (values provided depend on the selected category of BTC)		

Table 23. Example template for validation for red cells.

Minimum number of donations to be investigated: *enter number*

	Quality attribute	Acceptance criteria		Time of sampling	Additional information, if applicable
Active component and volume					
☐	Hemoglobin	*≥45*	g	*enter text*	*Quantity related to one unit*
☐	Hematocrit	*65 – 75*	%	*end of the shelf life*	*As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life.*

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	Category	Description/instruction	Parameter		Data field type	Legal basis	Additional reference
		☐ Volume	*230 - 330*	ml	*enter text*	*Including the volume of residual anticoagulant.*	
		☐ Mean corpuscular volume	*enter text*	*enter text*	*enter text*	*enter text*	
		☐ *enter text*	*enter text*	*enter text*	*enter text*	*enter text*	
		Stability parameters					
		☐ Hemolysis	*≤ 0,8*	%	*end of shelf life*	*% of red cells mass: As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life.* *As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life.*	
		☐ Supernatant K+	*enter text*	mmol/l	*enter text*	*enter text*	
		☐ ATP or 2,3-DPG or % of spherocytes	*enter text*	*enter text*	*enter text*	*enter text*	
		☐ pH	*enter text*	*enter text*	*enter text*	*enter text*	
		☐ Lactate	*enter text*	mmol/l	*enter text*	*enter text*	
		☐ Glucose	*enter text*	mmol/l	*enter text*	*enter text*	
		☐ pCO2	*enter text*	kPa	*enter text*	*enter text*	
		☐ pO2	*enter text*	kPa	*enter text*	*enter text*	
		☐ Red cells microvesicles	*enter text*	*enter text*	*enter text*	*enter text*	
		☐ 24-hour recovery	*enter text*	%	*enter text*	*enter text*	
		☐ Leachables from plastic film in supernatant and cells	*enter text*	*enter text*	*enter text*	*normally undertaken by the manufacturer*	
		☐ Osmotic fragility	*enter text*	*enter text*	*enter text*	*enter text*	
		☐ *enter text*	*enter text*	*enter text*	*enter text*	*enter text*	
		Purity and impurities					
		☐ Residual Leucocytes (× 10^6)	*≤ 1 x 106*	cells	*enter text*	*enter text*	
		☐ Other residual components	*enter text*	*enter text*	*enter text*	*enter text*	
		☐ *enter text*	*enter text*	*enter text*	*enter text*	*enter text*	
		Microbial growth					
		☐ Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*	*enter text*	*enter text*	

<table>
<tr><th></th><th>Category</th><th>Description/instruction</th><th>Parameter</th><th>Data field type</th><th>Legal basis</th><th>Additional reference</th></tr>
<tr><td></td><td></td><td>☐ enter text | enter text | enter text | enter text | enter text
Other
☐ enter text | enter text | enter text | enter text | enter text</td><td></td><td></td><td></td><td></td></tr>
<tr><td rowspan="2">3.6.2 Validation procedure</td><td rowspan="2">all</td><td rowspan="2">Validation procedure

If applicable, describe testing procedures used for validation should be provided. If appropriate, information on validation of procedures should be provided to demonstrate that the procedures are suitable for their intended purpose.</td><td>Quality attribute</td><td>text box</td><td rowspan="6">tabular format (0–∞ elements)

(template is provided in Table 24)</td><td rowspan="6"></td><td rowspan="6"></td></tr>
<tr><td>Testing laboratory</td><td>drop down

(values provided in section 1.2.6 of Module 1)</td></tr>
<tr><td>Procedure</td><td>text box</td></tr>
<tr><td>Validation protocol, if relevant</td><td>file box</td></tr>
<tr><td rowspan="2">Additional information, if applicable</td><td>text box</td></tr>
<tr><td>file box</td></tr>
<tr><td></td><td></td><td colspan="5">Table 24. Template for validation procedure.
<table>
<tr><th>Quality attribute</th><th>Testing laboratory</th><th>Procedure</th><th>Validation protocol, if relevant</th><th>Additional information, if applicable</th></tr>
<tr><td>enter text</td><td>- select -</td><td>enter text</td><td>descriptive file name | upload file</td><td>enter text
descriptive file name | upload file</td></tr>
<tr><td>…</td><td>…</td><td>…</td><td>…</td><td>…</td></tr>
</table></td></tr>
<tr><td></td><td>all</td><td>Narrative of validation</td><td></td><td>text box</td><td></td><td></td></tr>
</table>

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
		Provide a narrative of the validation, including identification of materials, equipment and operating conditions.					
		Alternatively, the narrative of validation can be uploaded		file box (1)			
3.6.3 Summary and conclusion of validation	all	Provide a summary (detailed summary) and overview (critical analysis, discussion and interpretation) of the validation data. Any important limitations of the available data should be discussed. In cases where the relevant guidelines were not followed, justification should be provided.		text box			
		Alternatively, the summary and conclusion of validation can be uploaded		file box (1)			
3.6.4 Validation reports	all	Provide validation results, raw data should be included	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			
3.6.5 Materials	all	Provide a list of materials, reagents and excipients involved in validation. Suitability of materials for the intended use should be clearly specified and evaluated.	Name	text box	tabular format (0–∞ elements)		
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			
			Description of the use in the process	text box			
			Additional information (e.g. reference document), if applicable	text box file box			
3.6.6 Equipment	all	Provide a list of equipment, instruments and devices, involved in validation. Suitability of equipment for the intended use should be clearly specified and evaluated.	Type of equipment (e.g. centrifuge)	text box	tabular format (0–∞ elements)		
			Name, model	text box			
			Art. no./cat. ref. no.	text box			
			Manufacturer	text box			

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	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
			Description of the use in the process	text box			
			Additional information (e.g. reference document), if applicable	text box			
				file box			

Module 4 – Non-clinical reports

4.1 Non-clinical reports

	Category	Description/instruction	Parameters	Data field type		Legal basis	Additional reference
	all (full application)	Provide non-clinical investigations and related information	N/A	N/A			
	all (bibliographic application)	Provide a detailed bibliography addressing all required non-clinical characteristics	N/A	N/A			
	all	Pharmacological/toxicological reports	Attachment	file box (1)	tabular format (0–∞ elements)		
			Additional information, if applicable	text box			
	all	Other reports	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

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Module 5 – Clinical reports

5.1 Clinical reports

	Category	Description/instruction	Parameter	Data field type		Legal basis	Additional reference
	all (full application)	Provide clinical investigations, clinical follow-up and related information. Information on clinical data sources and types can be found in Technical Annex 3.	N/A	N/A			D8.3 Ch. 3
	all (bibliographic application	Provide a detailed bibliography addressing all required clinical characteristics	N/A	N/A			
	all	Efficacy reports	Attachment	file box (1)	tabular format (0–∞ elements)		
			Additional information, if applicable	text box			
	all	Safety reports	Attachment	file box (1)	tabular format (0–∞ elements)		
			Additional information, if applicable	text box			
	all	Other reports	Descriptive document name	text box	tabular format (0–∞ elements)		
			Attachment	file box (1)			
			Additional information, if applicable	text box			

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ANNEX 3 Categories of blood, tissues and cells

	Active component	Preparation characteristics	Reference[a]
Blood	Whole blood	Whole blood	Part A.1
		Whole blood, leucocyte-depleted	Part A.2
	Red cells	Red cells	Part B.3
		Red cells, buffy coat removed	Part B.4
		Red cells, in additive solution	Part B.5
		Red cells, buffy coat removed, in additive solution	Part B.6
		Red cells, leucocyte-depleted	Part B.1
		Red cells, leucocyte-depleted, in additive solution	Part B.2
		Red cells, apheresis	Part B.7
		Red cells, washed	Part B.8
		Red cells, cryopreserved	Part B.9
		Red cells, irradiated	D6.1
		Red cells, other	
	Platelets	Platelets, recovered, single unit, in plasma	Part C.1
		Platelets, recovered, single unit, leucocyte-depleted	D6.1
		Platelets, recovered, pooled, in plasma	Part C.2
		Platelets, recovered, pooled, leucocyte-depleted, in plasma	Part C.3
		Platelets, recovered, pooled, in additive solution and plasma	Part C.4
		Platelets, recovered, pooled, leucocyte-depleted, in additive solution and plasma	Part C.5
		Platelets, recovered, pooled, pathogen-reduced	Part C.6
		Platelets, apheresis	Part C.7
		Platelets, apheresis, leucocyte-depleted	Part C.8
		Platelets, apheresis, in additive solution	Part C.9
		Platelets, apheresis, leucocyte-depleted, in additive solution	Part C.10
		Platelets, apheresis, pathogen-reduced	Part C.11
		Platelets, washed	Part C.12
		Platelets, cryopreserved	Part C.13
		Platelets, other	
	Plasma	Plasma, fresh frozen	Part D.1
		Plasma, fresh frozen, pathogen-reduced	Part D.2
		Cryoprecipitate	Part D.3
		Cryoprecipitate, pathogen-reduced	Part D.4
		Plasma, fresh frozen, cryoprecipitate-depleted	Part D.5
		Plasma, other	
	Granulocytes	Granulocytes, apheresis	Part E.1
		Granulocytes, pooled	Part E.2
		Granulocytes, other	
	Platelet concentrate	Platelet-rich plasma (PRP)	EUTC; TC Guide, Ch. 35.3
		Platelet-rich fibrin (PRF)	EUTC; TC Guide, Ch. 35.3

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			Platelet gel	EUTC; TC Guide, Ch. 35.3
			Platele lysate eye drops	TC Guide, Ch. 35.3
	Serum		Serum eye drops	TC Guide, Ch. 35.2
	Other			
Tissues/cells	Adipose,	tissue		Ch. 26
		cells		
	Cardiac,	tissue		
		cells		
	Cardiovascular,	valve	Cryopreserved heart valve allograft, antibiotic decontaminated	Part D
		vessel	Cryopreserved femoral artery allograft, antibiotic decontaminated	Part D
	Hematopoietic progenitor cells,	bone marrow	Haematopoietic progenitor cells from bone marrow – HPC(M)	Part D
		cord blood	Haematopoietic progenitor cells from umbilical cord blood – HPC(CB)	Part D
		peripheral blood	Haematopoietic progenitor cells from peripheral blood apheresis – HPC(A)	Part D
		other		
	Membrane,	amniotic	Amniotic membrane (AM) for biological dressing	Part D
		dura mater		
		fascia lata		
		fascia rectus		
		pericardium		
		other		
	Muscoskeletal,	bone	Cancellous bone chips	Part D
			Cortical bone struts	Part D
			Cryopreserved cortical bone	D6.1
			Cryopreserved cancellous bone	D6.1
			Dehydrated cancellous bone, viroinactivated, sterilised	D6.1
			Demineralized bone matrix (DBM), viroinactivated, sterilised	D6.1
		cartilage	Cryopreserved cartilage meniscus	D6.1
		ligament		
		tendon	Patellar tendon allograft	Part D
			Cryopreserved tendon	D6.1
		other		
	Neuronal,	nerve		
	Ocular,	conjunctival		
		corneal	Organ-cultured corneal donor tissue for (deep) anterior lamellar keratoplasty (ALK/DALK)	Part D
			Cold-stored corneal tissue for (deep) anterior lamellar keratoplasty (ALK/DALK)	Part D
			Organ-cultured corneal tissue for Descemet membrane endothelial keratoplasty (DMEK)	Part D
			Cold-stored corneal tissue for Descemet membrane endothelial keratoplasty (DMEK)	Part D
			Organ-cultured corneal tissue for Descemet stripping automated endothelial keratoplasty (DSAEK)	Part D

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			Cold-stored corneal tissue for Descemet stripping automated endothelial keratoplasty (DSAEK)	Part D
			Organ-cultured corneal tissue for penetrating keratoplasty (PK)	Part D
			Cold-stored corneal tissue for penetrating keratoplasty (PK)	Part D
		scleral		
		other		
	Other mature cells,	hepatocytes		
		keratinocytes		
		mononuclear cells	Mononuclear cells from unstimulated peripheral blood apheresis – MNC(A)	Part D
		T-cells		
	Pancreas,	pancreatic tissue		
		pancreatic islet cells		Ch. 24
	Parathyroid,	parathyroid		
	Reproductive,	ovarian tissue		Ch. 27
		testicular tissue		Ch. 27
	Skin,	dermis	Acellular dermal matrix (ADM)	Part D
		skin	Fresh skin allograft	D6.1
			Deep-frozen skin allograft	Part D
			Glycerol-preserved skin allograft	Part D
			Cryopreserved skin allograft	D6.1
			Lyophilized skin allograft	D6.1
	Umbilical cord,	tissue		
	Other			
Medically assisted reproduction	Reproductive,	gametes and embryos	Reproductive cells for medically assisted reproduction	

[a]References provided are the EDQM Blood Guide for blood and the EDQM Tissue/cell Guide for tissues/cells and MAR, unless otherwise stated.

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ANNEX 4 Example forms for quality control prior to release and validation

Example Template 1: Red blood cell quality control form for sub-subcategory "Red cells (RC)" derived from "7.1.2.1 Whole blood and red cells" in *D6-1 Preliminary final version v1-5.docx*

Table 21. Example template for quality controls prior to release for Red cells (RC).

	Quality attribute	Acceptance criteria		Frequency of control	Time of sampling	Additional information, if applicable
Active component(s)/constituent(s) and volume						
☒	Hemoglobin	≥ 45	g		*enter text*	Quantity related to one unit
☒	Hematocrit	65 – 75	%		end of the shelf life	As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life.
☒	Volume	230 - 330	ml		*enter text*	Including the volume of residual anticoagulant.
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Stability parameters						
☒	Hemolysis	≤ 0,8	%		end of shelf life	% of red cells mass: As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life. As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life.
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Purity and impurities						
☐	Residual Leucocytes (× 10^6)	*enter text*	*enter text*		*enter text*	*enter text*
☐	Other residual components	*enter text*	*enter text*		*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*

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Microbial growth						
☒	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*		*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Other						
☐	*enter text*	*enter text*	*enter text*	*100%*	*enter text*	*enter text*

Example Template 2: Red blood cell quality control form for sub-subcategory "Red cells leucocyte depleted in additive solution (RC LD AS)" derived from "7.1.2.1 Whole blood and red cells" in *D6-1 Preliminary final version v1-5.docx*

Table 21. Example template for quality controls prior to release for Red cells leucocyte depleted in additive solution (RC LD AS).

	Quality attribute	Acceptance criteria		Frequency of control	Time of sampling	Additional information, if applicable
Active Substance and volume						
☒	Hemoglobin	≥ 40	g		*enter text*	Quantity related to one unit
☒	Hematocrit	50 – 70	%		end of the shelf life	As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life.
☒	Volume	*enter text*	ml		*enter text*	Including the volume of residual anticoagulant.
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Stability parameters						
☒	Hemolysis	≤ 0,8	%		end of shelf life	% of red cells mass: As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life. As determined by SPC, a minimum of 90 % of units tested should meet the

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						required value at the end of the shelf life.
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Purity and impurities						
☒	Residual Leucocytes	≤ 1 x 10^6	cells		after processing	As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life.
☐	Other residual components	*enter text*	*enter text*		*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Microbial growth						
☒	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*		*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Other						
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*

Example Template 3: Platelet quality control template for sub-subcategory "Platelets, Recovered, Pooled, Leucocyte-Depleted, in Additive Solution (PRP LD AS)" derived from "7.1.2.2 Platelets" in *D6-1 Preliminary final version v1-5.docx*

Table 21. Example template for quality controls prior to release for Platelets, Recovered, Pooled, Leucocyte-Depleted, in Additive Solution (PRP LD AS).

	Quality attribute	Acceptance criteria		Frequency of control	Time of sampling	Additional information, if applicable
Active Substance and volume						
☒	Platelet content	≥ 2.0	x 10^{11} platelets	*enter text*	*enter text*	Quantity related to one unit. As determined by SPC, a minimum of 90 % of units tested should meet the required value.

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☒	Volume	*enter text*	ml	*enter text*	*enter text*	Including the volume of residual anticoagulant solution. 40 ml per 0.6 × 10^{11} of platelets. As determined by SPC, a minimum of 90 % of units tested should meet the required value.
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Stability parameters

☒	pH	≥ 6.4		*enter text*	end of shelf life	As determined by SPC, all tested units must comply. pH measured (+ 22 °C) at the end of the recommended shelf-life. Measurement of the pH in a closed system is preferable to prevent CO_2 escape. Measurement may be made at another temperature and then corrected.
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*

Purity and impurities

☒	Residual Leucocytes	≤ 1 x 10^6	cells		after processing	As determined by SPC, a minimum of 90 % of units tested should meet the required value at the end of the shelf life.
☐	Other residual components	*enter text*	*enter text*		*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*

Microbial growth

☒	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*		*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*

Other

☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*

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Example Template 4: Platelet quality control form for sub-subcategory "Apheresis Platelets, Leucocyte-Depleted (AP LD)" derived from "7.1.2.2 Platelets" in *D6-1 Preliminary final version v1-5.docx*

Table 21. Example template for quality controls prior to release for Apheresis Platelets, Leucocyte-Depleted (AP LD) Standard Unit

	Quality attribute	Acceptance criteria		Frequency of control	Time of sampling	Additional information, if applicable
Active Substance and volume						
☐	Platelet content	≥ 2.0	x 10^{11} platelets	*enter text*	*enter text*	Quantity related to one unit. As determined by SPC, a minimum of 90 % of units tested should meet the required value.
☐	Platelet content for neonates and infants	≥ 0.5	x 10^{11} platelets	*enter text*	*enter text*	Quantity related to one unit. As determined by SPC, a minimum of 90 % of units tested should meet the required value.
☐	Volume	*enter text*	ml	*enter text*	*enter text*	Including the volume of residual anticoagulant solution. 40 ml per 0.6 × 10^{11} of platelets. As determined by SPC, a minimum of 90 % of units tested should meet the required value.
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
Stability parameters						
☐	pH	≥ 6.4		*enter text*	end of shelf life	As determined by SPC, all tested units must comply. pH measured (+ 22 °C) at the end of the recommended shelf-life. Measurement of the pH in a closed system is preferable to prevent CO_2 escape. Measurement may be made at another temperature and then corrected.
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Purity and impurities						
☒	Residual Leucocytes	≤ 1 x 10^6	cells		after processing	As determined by SPC, a minimum of 90 % of units tested should meet the

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						required value at the end of the shelf life.
☐	Other residual components	*enter text*	*enter text*		*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Microbial growth						
☒	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*		*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*
Other						
☐	*enter text*	*enter text*	*enter text*		*enter text*	*enter text*

Example Template 5: Plasma quality control form for sub-subcategory "Fresh Frozen Plasma (FFP) Quarantine" derived from "7.1.2.3 Plasma and cryoprecipitate" in *D6-1 Preliminary final version v1-5.docx and Blood Guide, 20th ed.*

Table 21. Example template for quality controls prior to release for Fresh Frozen Plasma (FFP) Quarantine.

	Quality attribute	Acceptance criteria		Frequency of control	Time of sampling	Additional information, if applicable
Active Substance and volume						
☒	Factor VIII activity	≥ 70	IU / 100 ml	*enter text*	*enter text*	Factor VIII content: Average (after freezing and thawing). As determined by SPC, a minimum of 90 % of units tested should meet the required value.
☐	Fibrinogen	*enter text*	g/l	*enter text*	*enter text*	*enter text*
☒	Volume	*enter text*	ml	*enter text*	*enter text*	Stated volume ± 10 %. Including the volume of residual anticoagulant solution.
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
Stability parameters						

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☐	Factor VIII activity	≥ 70	IU / 100 ml	*enter text*	First month after freezing and end of shelf life	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Purity and impurities

☒	Residual Leucocytes	≤ 100 x 10^6	cells	*enter text*	*enter text*	Quantity related to one unit. As determined by SPC, a minimum of 90 % of units tested should meet the required value.
☒	Residual Platelets	≤ 50 x 10^9	platelets	*enter text*	*enter text*	Quantity related to one unit. As determined by SPC, a minimum of 90 % of units tested should meet the required value.
☒	Residual Red Cells	≤ 6.0 x 10^9	cells	*enter text*	*enter text*	Quantity related to one unit. As determined by SPC, a minimum of 90 % of units tested should meet the required value.
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Microbial growth

☒	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Infectious disease markers

☒	Anti-HIV 1 & 2	Negative	by approved screening test	100 %	end of the FFP quarantine period	Donor check at the end of the FFP quarantine period of 6 month.
☒	HBsAg	Negative	by approved screening test	100 %	end of the FFP quarantine period	Donor check at the end of the FFP quarantine period of 6 month.
☒	Anti-HCV	Negative	by approved screening test	100 %	end of the FFP quarantine period	Donor check at the end of the FFP quarantine period of 6 month.
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

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☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Other

☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Example Template 6: HPC quality control form for sub-subcategory "Haematopoietic progenitor cells from peripheral blood apheresis – HPC(A)" derived from "7.2.2 Specification/ Critical Quality Attributes of HSC, Bone Marrow, Apheresis, Cord Blood, Mononuclear Cells – Table 2" in *D6-1 Preliminary final version v1-5.docx and Tissues and Cells Guide, 4th ed.*

Table 21. Example template for quality controls prior to release for Haematopoietic progenitor cells from peripheral blood apheresis – HPC(A).

	Quality attribute	Acceptance criteria		Frequency of control	Time of sampling	Additional information, if applicable
Active Substance and volume						
☒	for autologous transplantation: Viable $CD34_+$ cell dose	≥ 2.0	× 10^6/kg	*enter text*	*enter text*	Quantity related to recipient body weight
☒	for allogeneic transplantation: Target viable CD34+ cell dose (approximately): – Minimum viable CD34+ cell dose: 1.5-3.5 × 106/kg body weight.	>5.0	× 10^6/kg	*enter text*	*enter text*	Quantity related to recipient body weight
☒	for allogeneic transplantation: Minimum viable CD34+ cell dose	1.5-3.5	× 10^6/kg	*enter text*	*enter text*	Quantity related to recipient body weight
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
Stability parameters						
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
Purity and impurities						

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☒	In case of ABO incompatibility: Red cell volume	< 1	ml/kg	*enter text*	*enter text*	Quantity related to recipient body weight
☒	In case of cryopreserved HPC(A): DMSO volume	< 1	ml/kg	*enter text*	*enter text*	Quantity related to recipient body weight
☐		*enter text*	*enter text*	*enter text*	*enter text*	
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
Microbial growth						
☒	Aerobic or anaerobic bacteria, and yeast or fungi	No evidence of microbial growth	*enter text*	*enter text*	*enter text*	The presence of microbial contamination may not preclude release but may indicate the need for antibiotic treatment in the recipient.
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
Other						
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Example Template 7: Validation form for subcategory "Platelet concentrates" derived from "2.2.4 Evaluation of platelet components for transfusion" in *D6-1 Preliminary final version v1-5.docx.*

Table 23. Template for validation procedure for platelet concentrates.

Minimum number of donations to be investigated: *enter number*

	Quality attribute	Acceptance criteria		Time of sampling	Additional information, if applicable
Active Substance and volume					
☐	Platelet content	≥ *enter text*	x 10^{11}	*enter text*	Quantity related to one unit
☐	Platelet Concentration	*enter text*	x 10^{9}	*enter text*	*enter text*

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☐	Volume	230 - 330	ml	Day 1	Including the volume of residual anticoagulant.
☐	MPV (Mean platelets volume)	*enter text*	fl	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Stability parameters

☐	pH	*enter text*	*enter text*	*enter text*	*enter text*
☐	Morphology, e.g. swirl score	*enter text*	*enter text*	*enter text*	*enter text*
☐	Activation, e.g. beta thromboglobulin, CD62P (expression or soluble)	*enter text*	*enter text*	*enter text*	*enter text*
☐	Lysis, e.g. LDH	*enter text*	*enter text*	*enter text*	*enter text*
☐	Metabolic activity: ATP, pH, Lactate, Glucose, pCO2, pO2				
☐	Function e.g. Aggregation Thromboelastography/ Thromboelastometry	*enter text*	mmol/l	*enter text*	*enter text*
☐	Cytokines/chemokines	*enter text*	kPa	*enter text*	*enter text*
☐	Platelet microvesicles	*enter text*	kPa	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Purity and impurities

☐	Residual WBC	*enter text*	*enter text*	Day 1	*enter text*
☐	Residual Red Cell Count	*enter text*	*enter text*	Day 1	*enter text*
☐	Plasma /PAS ratio	*enter text*	*enter text*	Day 1	*enter text*
☐	Residual content of "added substances"	*enter text*	*enter text*	*enter text*	*enter text*
☐	Leachables from plastic film in supernatant and cells	*enter text*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Microbial growth

☐	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Other

☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

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Example Template 8: Validation form for subcategory "Plasma for transfusion" derived from "2.2.5 Evaluation of plasma for transfusion" in *D6-1 Preliminary final version v1-5.docx.*

Table 23. Template for validation procedure for plasma for transfusion.

Minimum number of donations to be investigated: *enter number*

	Quality attribute	Acceptance criteria		Time of sampling	Additional information, if applicable
Active Substance and volume					
☒	Protein after thawing		g/l	*enter text*	*enter text*
☒	Immunoglobulin (G, M, A)		g/l	*enter text*	*enter text*
☒	Volume		ml	*enter text*	Including the volume of residual anticoagulant.
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
Stability parameters					
☒	FVIII:C	*enter text*	IU/ml	*enter text*	*enter text*
☐	PT ratio (Prothrombin time)	*enter text*	*enter text*	*enter text*	*enter text*
☐	Thromboelastography/ Thromboelastometry	*enter text*	*enter text*	*enter text*	*enter text*
☐	APTT ratio	*enter text*	*enter text*	*enter text*	*enter text*
☐	Fibrinogen	*enter text*	g/l	*enter text*	*enter text*
☐	FII, V, VII, IX, X, XI, (UI/mL)	*enter text*	IU/ml	*enter text*	*enter text*
☐	vWf:Ag	*enter text*	*enter text*	*enter text*	*enter text*
☐	vWf:RiCof	*enter text*	*enter text*	*enter text*	*enter text*
☐	AT III (Antithrombin), Protein C, Protein S	*enter text*	*enter text*	*enter text*	*enter text*
☐	TAT/Frag1.2/FPA + FXIIa	*enter text*	*enter text*	*enter text*	*enter text*
☐	C3a (mg/L) and C5a (µg/L)	*enter text*	*enter text*	*enter text*	*enter text*

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☐	C1 inhibitor	*enter text*	*enter text*	*enter text*	*enter text*
☐	Alpha-2 anti-plasmin	*enter text*	*enter text*	*enter text*	*enter text*
☐	Plasminogen	*enter text*	*enter text*	*enter text*	*enter text*
☐	ADAMTS13	*enter text*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Purity and impurities

☐	Residual Leucocytes WBC	*enter text*	*enter text*	Day 1	*enter text*
☐	Residual Platelets	*enter text*	*enter text*	Day 1	*enter text*
☐	Residual Red cells	*enter text*	*enter text*	Day 1	*enter text*
☐	Leachables from plastic film				
☐	Residual concentration of "added substances"				
☐	Other residual components				
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Microbial growth

☐	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Other

☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Example Template 9: Validation form for subcategory "Haematopoietic progenitor cells (HPC)" derived from "3.2.3 Haematopoietic progenitor cells (HPC) processing" in *D6-1 Preliminary final version v1-5.docx.*

Table 23. Template for validation procedure for Haematopoietic progenitor cells (HPC).

Minimum number of donations to be investigated: *enter number*

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	Quality attribute	Acceptance criteria		Time of sampling	Additional information, if applicable
Active Substance and volume					
☐	TNC count in the starting material	*enter text*	*enter text*	*enter text*	except for CB
☐	TNC viability in the starting material	*enter text*	*enter text*	*enter text*	except for CB
☐	TNC count	*enter text*	*enter text*	before and after cryopreservation	as applicable
☐	TNC viability	*enter text*	*enter text*	before and after cryopreservation	as applicable
☐	CD34+ or CD3+ count in the starting material	*enter text*	*enter text*	*enter text*	except for CB
☐	Viable CD34+ counts	*enter text*	*enter text*	before and after cryopreservation	as applicable
☐	Viable MNC counts	*enter text*	*enter text*	before and after cryopreservation	as applicable
☐	MNC viability	*enter text*	*enter text*	before and after cryopreservation	as applicable
☐	CD34+ or CD3+ viability	*enter text*	*enter text*	before and after cryopreservation	as applicable
☐	Volume	*enter text*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*
Stability parameters					
☐	CFU growth after thawing	*enter text*	*enter text*	*enter text*	*enter text*
☐	CD45 cell viability	*enter text*	*enter text*	*enter text*	*enter text*

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☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Purity and impurities

☐	Platelet count in the starting material	*enter text*	*enter text*	*enter text*	*enter text*
☐	Haematocrit in the starting material	*enter text*	*enter text*	*enter text*	*enter text*
☐	Granulocytes count in the starting material	*enter text*	*enter text*	*enter text*	*enter text*
☐	Nucleated RBCs (erythroblasts for cord blood)	*enter text*	*enter text*	before cryopreservation	*enter text*
☐	If CD34+ selection is performed, then count CD3+	*enter text*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Microbial growth

☐	Aerobic or anaerobic bacteria, and yeast or fungi	*No evidence of microbial growth*	*enter text*	*enter text*	*enter text*
☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

Other

☐	*enter text*	*enter text*	*enter text*	*enter text*	*enter text*

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ANNEX 5 List of contributing experts

The following experts contributed to this document by comments, discussion and ideas

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