IT-Support Requirement Catalog for Biobank Management

A) Module "Organization and Operation of a Biobank"

12 requirement categories were defined and detailed requirements were described to support the role of a "Biobank Operator/Manager":

1. Master Data Management (Projects / Institutions / Persons)

As per context and application area, biospecimens can be collected in a biobank in a project-related and/or institution-related and/or person-related way. Hybrid forms of the types described above are also possible. Institutions and persons can either act and be maintained as institutions providing samples or as inquiring institutions using samples within research projects. It should also be possible for institutions/persons only to be maintained as inquiring/using institutions in a biobank. In case of a pure biobank operator without own scientific research interests, the staff of this institution neither are inquiring nor using persons. The subsequently defined functions therefore need to support all the above characterizations:

1.1. Entry and processing of projects by means of an interactive entry dialog box

1.2. Entry and processing of institutions by means of an interactive entry dialog box

1.3. Entry and processing of persons by means of an interactive entry dialog box

1.4. Assignment of institutions to projects

1.5. Assignment of persons to institutions/projects

1.6. Assignment of persons to a biobank

1.7. Assignment of persons and/or institutions to roles (with a correspondingly stored authorization concept). The three major roles are the following:

1.7.1. Persons/institutions who store biospecimens in a biobank

1.7.2. Persons/institutions who are authorized to order biospecimens from a biobank

1.7.3. Persons who are authorized to handle bio specimens in a biobank or who are assigned specific functions in the biobank

1.8. Processing of the assignments between persons, institutions and projects

1.9. Deletion of assignments between persons, institutions and projects

1.10. Deletion of persons, institutions and projects (in consideration of all consistency rules for the data base)

2. Master Data Management (Physical Storage Locations)

Configuration and maintenance of master data on physical storage locations where biospecimens are stored:

2.1. Hierarchical structuring of physical storage locations (in consideration of access rights and client definitions)

2.1.1. Dynamically extendable structure of physical storage locations; at best with an unlimited multilevel hierarchy (at least 6 levels: e.g. city, building, refrigerator, shelf, rack, box, line, column)

2.1.2. Breakdown to individual physical storage location via Explorer functions

2.1.3. Breakdown to individual physical storage location via graphic support

2.1.4. Possibility to define templates (e.g. for complete refrigerators or individual types of racks)

2.2. Create, process and delete physical storage locations (in consideration of all consistency rules for the data base)

3. Sampling, Pre-Analytics, Sample Delivery and Sample Aliquoting

3.1. Complete documentation of a biospecimen´s logistic chain from sampling to storage in the biobank

3.1.1. Directly via an interactive entry dialog box

3.1.2. Via an import interface

3.2. Documentation of pre-analytic and quality-assuring aspects during sampling of the biospecimens

3.2.1. Documentation of the sampling date

3.2.2. Documentation of the quality assuring measures (compliance with SOPs etc.)

3.2.3. Documentation of a test person's condition upon sampling (clinical annotation)

3.2.3.1. Interactive documentation via internal entry dialog box

3.2.3.2. Importing of annotation data from an external data source

3.2.3.3. Linkage with data that already exist in an external data source and that were documented on the test person's condition

3.3. Documentation of sample processing at the sampling location subject to the material

3.4. Documentation of quality assurance during storage of the samples (interim storage) and sample processing at the withdrawal location

3.5. Creation of auxiliary means for an unambiguous sample identification and sample assignment (e.g. by means of a barcode, 2D-barcode)

3.6. Documentation/monitoring of quality assuring measures during transportation of the samples (e.g. temperature logger)

3.6.1. Documentation of organizational requirements related to the sample transportation subject to the hazard class

3.6.2. Documentation of implemented organizational measures during transportation of samples

3.7. Documentation of incoming samples

3.7.1. Sample identification (e.g. by means of a barcode)

3.7.2. Possibility to subsequently interactively record concomitant sample information (e.g. nature, origin, quantity and quality of the material and affiliation to a project)

3.7.3. Possibility to electronically import concomitant sample information (e.g. nature, origin, quantity and quality of the material and affiliation to a project) by means of an interface from an external system

3.7.4. EDP-supported sample quality examination and documentation of incoming samples (e.g. by means of documenting severe adverse events such as "Sample is defrosted", "Container is open")

3.8. Automated initiation of measures upon loss or damage of a biospecimen during transportation

3.8.1. Information of the parties concerned (mainly sender and recipient)

3.8.2. Error documentation and investigation

3.9. Monitoring, documentation and quality control of the automated sample aliquoting by using e.g.:

3.9.1. Primary/secondary test tubes (e.g. by means of 1D-/2D-Barcode, RFID)

3.9.2. Storage boxes (e.g. by means of 1D-/2D-Barcode, RFID), straws etc.

3.10. Linkage of newly created aliquots with their corresponding original samples

3.11. Control, monitoring, documentation of sample aliquoting by means of automated liquid handling systems (EDP-supported process automation)

3.12. Documentation of quality assured reprocessing of different materials, in particular regarding e.g. DNA, RNA, serum/plasma, urine, liquor, tissue, cells

4. Sample Administration and Management

4.1. Storage documentation of biospecimens

4.1.1. Drilldown to individual physical storage locations via Explorer functions

4.1.2. Drilldown to individual physical storage locations via graphic support

4.1.3. Assignment of the physical storage location to a biospecimen:

4.1.3.1. Current unambiguous storage location in the biobank

4.1.4. Direct display of sample information such as, for example, nature, origin, quantity still available, already used quantity, number of freezing/defrosting cycles and affiliation to a project

4.1.4.1. directly via pop-ups

4.1.4.2. via submenus

4.1.5. Definition of retention periods and retention specifications for specific samples

4.1.5.1. by the providing scientist

4.1.5.2. by the biobank (quality, law, consent, organization)

4.1.6. Display of sample information upon revocation of the proband´s informed consent (note on destruction, date, responsible person etc.)

4.1.7. Automated documentation for storage of larger quantities of biospecimens (e.g. a whole rack or a whole box with aliquots)

4.1.8. Maintaining the storage history of a biospecimen (time/duration, place, temperature)

4.1.9. Documentation of freezing and defrosting processes for a biospecimen (time, frequency); also for unscheduled events (e.g. power failure)

4.1.9.1. Linkage with the temperature logger of a physical storage location

4.1.10. Documentation of material delivery from the biobank:

4.1.10.1. Date

4.1.10.2. Quantity

4.1.10.3. Purpose

4.1.10.4. Quality of the sample delivered

4.1.10.5. Complementary parameters

5. Status Query regarding stored Biospecimens

5.1. Provision of analysis/reports for different research questions; filtered/sorted by project or sample provider / requesting party, for example:

5.1.1. Which biospecimens/aliquots (quantity, material, quality etc.) of a specific patient/project are still available?

5.1.2. Into how many sub materials was a sample divided (e.g. by means of aliquoting)?

5.1.3. Which samples/aliquots were already delivered?

5.1.3.1. to whom?

5.1.3.2. when (date)?

5.1.3.3. which materials?

5.1.3.4. for which research question, on which diseases, for which purpose (namely for which types of analysis)?

5.2. Based on particular retention periods/specifications (of different levels) it may occur that samples with the strictest retention specifications are not viewed at all as available during the time they are blocked and that samples with less strict retention specifications are viewed, however, by listing them as samples currently blocked.

5.3. Based on the corresponding user rights, it must be possible to restrict evaluations/queries in a user-dependent way to projects or stored samples.

5.4. Which information from the analysis already performed with a particular sample is available? By means of which analysis methods were those results established? What is the quality of the data? etc.

6. Status Query on the general Biospecimen Stock or on the Status of available Physical Storage Locations

6.1. Overview on the biospecimen stock of a physical storage location (e.g. in form of a list, a diagram or by means of Explorer functionality)

6.2. if required, the hit list is to be filtered in terms of access policies to the material (policies, data sharing)

6.3. Overview of all physical storage locations of biobank together with the still available free physical storage locations

7. Quality Control

7.1. Documentation of quality assurance parameters to monitor parameters such as the storage temperature over a specified period of time

7.1.1. directly by means of an interactive entry dialog box

7.1.2. via import interfaces:
logging of the overall sample processing process by transferring data from automated processes

7.2. Automated initiation and documentation of damage concepts in the event of a failure of the storage technology, e.g. via an interface to access the building equipment and appliances technologies

7.3. Review and documentation of the sample quality and storage quality after a long-term storage by automated transfer of quality parameters (measured values) after a recovery of the sample. Data transfer of QM parameters should be supported by a bidirectional interface to a laboratory information system so that the measurement of QM parameters is possible directly from the biobank software)

7.4. Documentation and detection of an inaccurate storage (identification error, quality error)

7.5. Documentation of the criteria to examine a sample prior to a delivery to a third party

8. Sample Request

8.1. Documentation of publication policies for using biospecimens in cooperation (e.g. project-specific policies)

8.2. Recording of the request for delivery of a sample to a third party (nature, quantity, quality, purpose of use, recipient):

8.2.1. Online form; with direct data transfer into a database and initiation of an automated approval workflow

8.2.2. In writing, subsequently for example via document management, scanner, electronic recording of form

8.3. Support of a workflow-based application and approval procedure by means of which the "request for use of a scientist/a research group" can be submitted in a well-prepared way to a decision-making body to decide on the release of its use:

8.3.1. Data entry form to describe a request to use biospecimens for a research project

8.3.1.1. including a list of all biospecimens to be used for this specific research project

8.3.1.2. including a list if thereafter specific biospecimens "are finally used up" or not; or a list of how many "similar" biospecimens are still available after delivery

8.3.2. Possibility to view publication policies for the use of biospecimens

8.3.3. Creation of a list of research projects that were already applied for (refused/implemented) and on biospecimens released and delivered to the applicants of the current application and on similar research applications of other applicants

8.3.4. Possibility to define an approval/refusal workflow between applicant and approving body

8.3.5. Support of an electronic voting procedure for the approving body

8.3.6. Workflow for feedback of the outcome of an application/approval workflow to the applicant and the administrator of the biobank so that the latter can prepare the delivery/sending of the biospecimens (in case of an approval)

8.3.7. Consideration of the fact that the administrator/owner of the samples does not want to disclose the ownership of particular samples. This means that the system should support the establishement of a first anonymous communication between the inquiring party and the owner of a set of samples (without the inquiring party knowing who owns the required samples in the beginning)

9. Shipment of Samples

9.1. Complete documentation of the transportation chain of a biospecimen from the biobank to the requesting scientist

9.1.1. directly via an interactive entry dialog box

9.1.2. via an import interface

9.2. Support of postal shipments → printing of labels, barcode scanner, franking

9.3. Possibility to monitor the status of a shipped biospecimen on its transportation route

9.4. Documentation of the incoming material at the recipient of the biospecimen

9.4.1. Confirmation of receipt in consideration of defined criteria on the sample quality

10. Administration of Results obtained from the Samples

10.1. Automated import of sample data

10.2. Assignment of sample data on a defined sample aliquot

10.3. Recording of "intellectual properties" on the sample data

10.4. Procurement of sample analysis results or contact data to a scientist requesting samples, in case the latter wants to perform analysis on which analysis results do already exist

10.5. As for the storage and the physical storage location of the sample data imported in accordance with 10.1, the data privacy protection recommendations for biobanks of the TMF e.V. are to be considered

11. Support of basic Services and Routine Processes of a Biobank

11.1. Printouts for barcode parcel labels which comprise specific data about the sample (similar to the Lab-ID defined in the TMF data security concept), but do not disclose any identifying information to a bystander. Also applicable for 9.2

11.2. Possibility to manage and view SOPs (project-specific) to use the biobank

11.2.1. Creation and modification of SOPs (versioning, approval depending on the rights granted, archiving, etc.) for example by means of a document management system

11.3. Possibility to manage and view standard forms/documents on general laws, rules and regulations and outline conditions for the use of biospecimens in research projects

11.4. If the documents mentioned as under 11.2 are provided also in electronic terms by a superimposed central authority, an update mechanism can be provided to download the latest documents from the central authority or to establish a corresponding link. Thus it is to be guaranteed that guidelines, forms and even functions within the software are always kept in line with current ethics, law and technology standards

12. Documentation of the modified Storage/Use Approval (Revocation or Extension) of Samples from Patients/Probands/Donators and Initiation of Follow-Up Actions

12.1. Storage of Email (addresses) of the patient/donator

12.2. Possibility of establishing a contact

12.2.1. in the event of a required extension of the research usage specificaion

12.2.2. to initiate a personal result notification

12.2.3. to request another sample provision

12.3. User interface for the patient to inspect and maintain his/her data

12.4. User interface for the patient to revoke his informed consent declaration

12.5. Workflow functions to trigger all required activities in an automated way if a patient/test person makes use of the functions in line with 12.3/12.4

12.6. As for the storage and the physical storage location of the person-related data to be stored in accordance with this request, the recommendations of the data privacy concept for biobanks of the TMF are to be considered. In terms of organization, we recommend to additionally include a data trustee in the event of communication processes with the patient

B) Module "Sample Requests by Researchers"

For the purpose of research with regard to suitable patient populations and the subsequent request of samples by a researcher, we assume that a suitable annotation database with querying functions (to be characterized in detail in the following) is available. Normally, such an annotation database is filled based on import processes from a corresponding primary documentation database (see C). In support of the role "Researcher requesting Samples", 3 requirement categories were defined and described in detail:

1. An intuitive user interface shall be provided for authorized research groups, supporting querying and filtering of patient subpopulations based on particular clinical characteristics (e.g. query-by-example-methodology and showing the resulting number of hits)

1.1. Possibilities to define and manage an ontology on characteristics used in clinical annotation

1.2. Listing of all annotation characteristics (in a hierarchical way similar to the MS-Windows-Explorer tree) by means of which the overall patient population of a project can be filtered

1.3. User-friendly interface to define a research query (Query/Filter):

1.3.1. Possibility to select a specific catalog item (or a set of catalog items) for every annotation characteristic to be used in a query

1.3.2. Possibility to negate on catalog items or a set of catalog items

1.3.3. Possibility to establish multiple query restrictions by means of an AND-operator

1.3.4. Possibility to establish multiple query restrictions by means of an OR-operator

1.3.5. Possibility for nested filtering based on already filtered sub populations

1.4. Clearly-arranged display of search result

1.5. Possibility to store once defined filters (queries):

1.5.1. User-specific

1.5.2. Project-specific

1.6. Possibility to store once searched sub populations:

1.6.1. User-specific

1.6.2. Project-specific

2. It should be possible to determine for selected patient populations which quantities of biospecimens of a specific type are stored in which physical storage locations of the biobank

2.1. Possibility to create a list of all available biospecimens on a pre-defined patient sub population

2.2. Possibility to create a list of all storage locations based on a list of biospecimens created beforehand (authorization potentially restricted to the biobank operator)

3. Creation of a Sample Request (see its further processing as under 9.3 in the module "Organization and Operation of a Biobank")

3.1. Possibility to document further information describing a research request/sample request (to complement the list of bio specimens created as under 2.1)

3.2. Possibility to initiate a corresponding workflow to check the release approval of a sample request

C) Module "Documentation of Clinical Annotations"

Specifications 1 to 9 quoted hereinafter should be provided by the primary clinical (or research) information system where the documentation of the patients/probands takes place (e.g. the electronic medical record system or the study management system). Requirements 10 and 11 apply to the corresponding annotation database into which the contents of the primary documentation are transferred.

1. The software product comprises a pre-defined annotation database and associated documentation forms
2. Possibility to freely design data entry dialog boxes for clinical annotation purposes
   2.1. also by the user himself/herself with a correspondingly user-friendly form generator tool
3. Data entry forms for clinical annotation can be defined in a project-related manner
4. Possibility to define plausibility tests for the data entry fields for the clinical annotation
5. Possibility to define "large catalogs" (both internationally/nationally standardized catalogs such as ICD, ICPM, Mesh, ICD-O and own in-house catalogs) and to import them as data entry selection items via CSV-data files
6. Possibility to store relationships between attributes of different catalogs
7. Graphic annotation for example based on integrated anatomic graphics

8. Semi-automatic generation of graphical genealogical trees by the user
9. Possibility to export data for the annotations database. Export formats
    9.1. CSV
    9.2. Excel
    9.3. Ascii
    9.4. CDISC
    9.5. other formats
10. Possibility to import data into the annotation database. Import formats
    10.1. CSV
    10.2. Excel
    10.3. Ascii
    10.4. CDISC
    10.5. other formats
11. Verify compliance with all predefined plausibility rules and data entry catalogs also in the case of an automated import into the annotation database