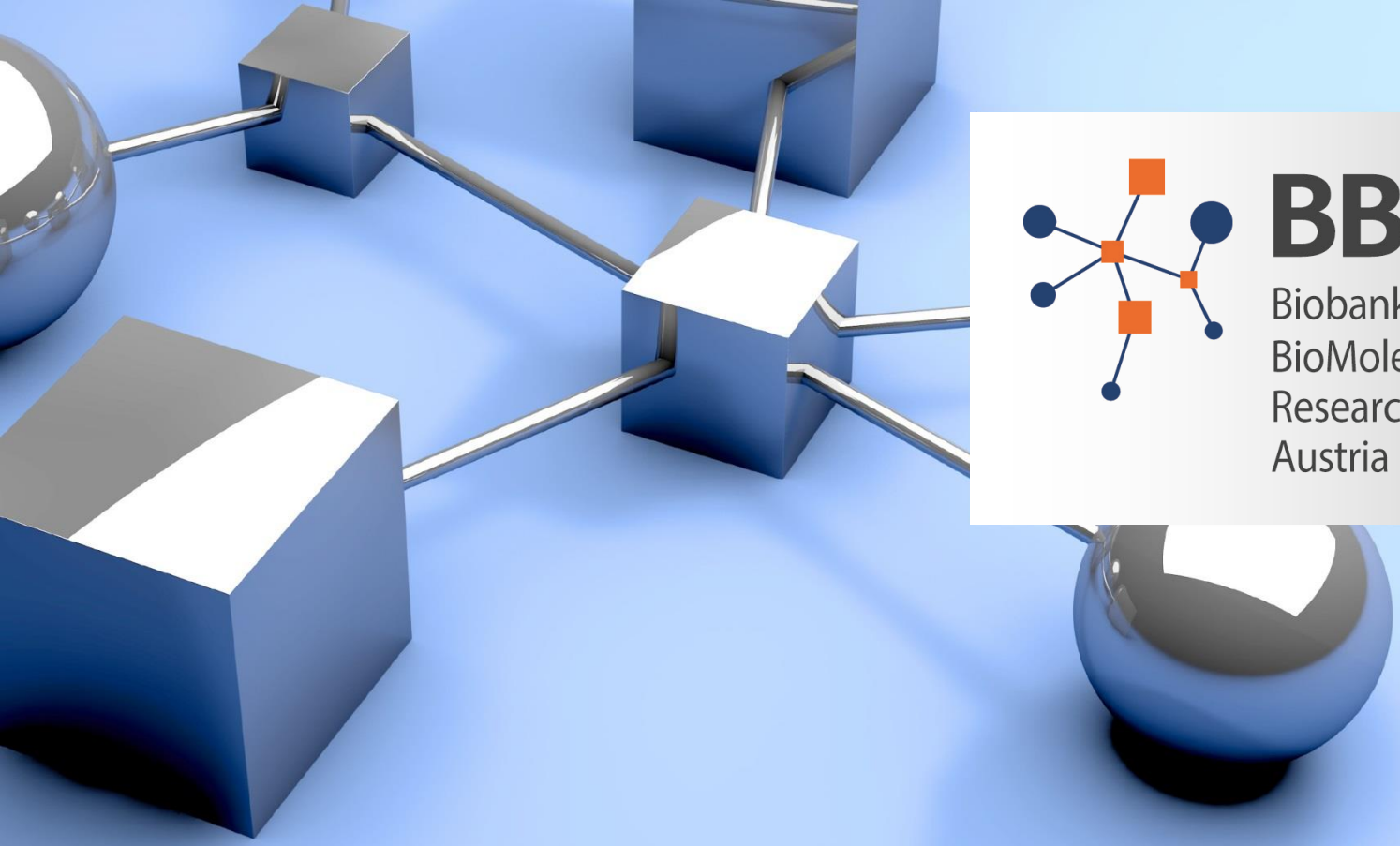

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Defining and Capturing Process Quality in RD-Connect

Heimo Müller, Robert Reihs

Berlin, 19 February 2015

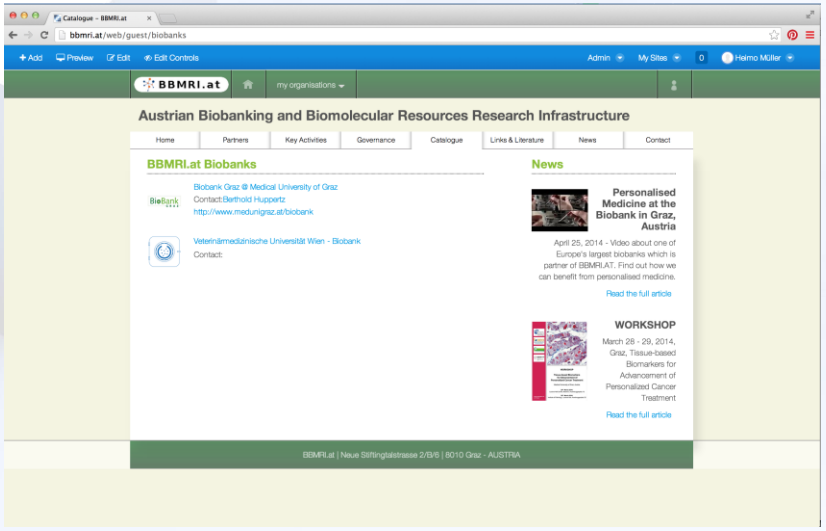
catalogue.rd-connect.eu
www.bbmri.at

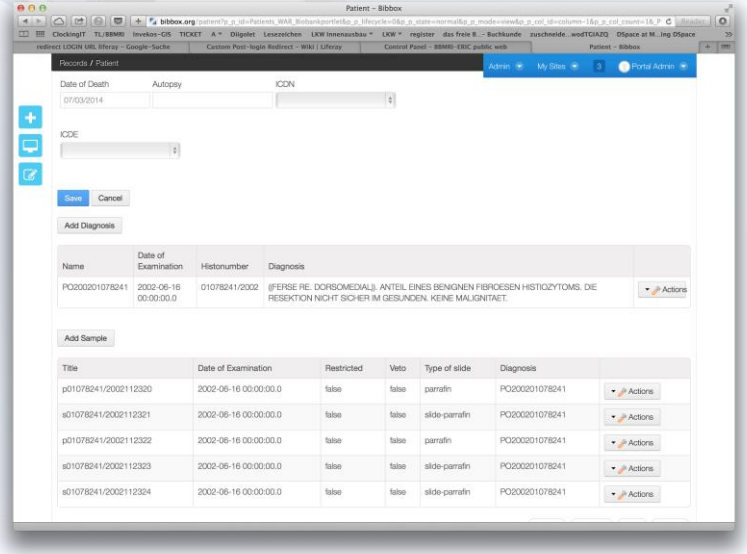
Objectives

- To build a map of RD biobanks starting from European biobank networks already established with EU support and large networks outside Europe
- To provide a common portal (ID card) for biobanks and registries
- Motivate biobanks and registries to self-maintain their ID card
- Analyse questionares
- Provide an interface (human and machine readable) to the database

Current ID-Card Portal

- Software Components from different projects
  - RD-Connect, BBMRI.at, BBMRI-LPC, BioMedBridges, BibBoX





Mapping of RD-Connect

- Mapping of 2074 registries and 608 biobanks from several sources done

  EuroBioBank, BBMRI, Orphanet,, Neuromics, Epirare, Eurocat, SCNIR,hqip,cordis, treat nmd, edfs, ….

- Remove duplicates and review unified list:
  981 registries / 506 biobanks
- ID Card System with a Core Implementation Group (CIG)
- Roll-Out started end of October 2014 with first Biobanks and Registreis
  - 94 Registries Invited
  - Biobank Panel Assessment established

Current ID-Card Portal

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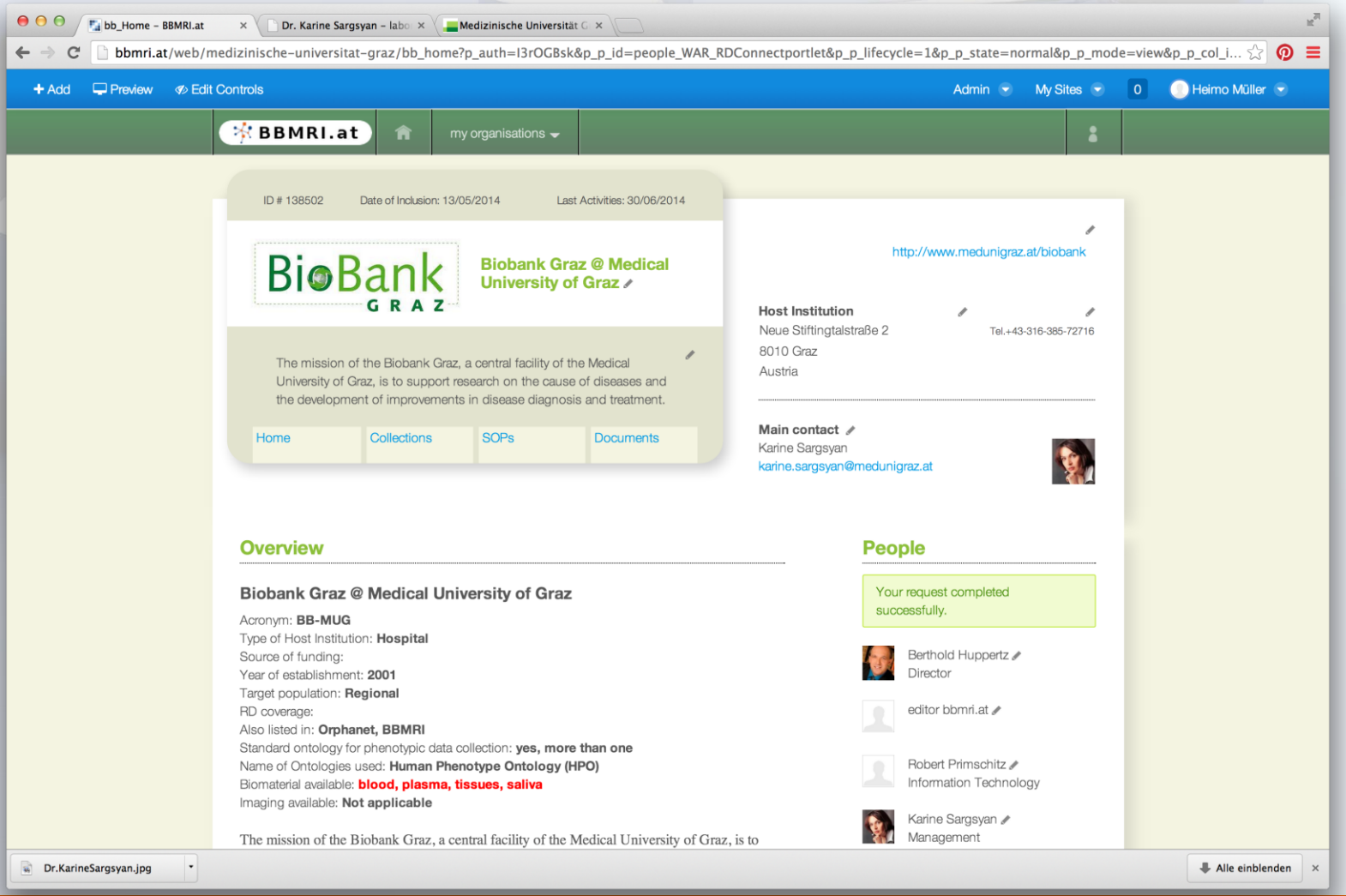

RD-Connect ID-Card

- Overview of all Registries/Biobanks in the Catalogue
- Recent activities of Registries/Biobanks
- Search for Disease codes
  - ORPHA52
  - Dent disease

Current ID-Card Portal

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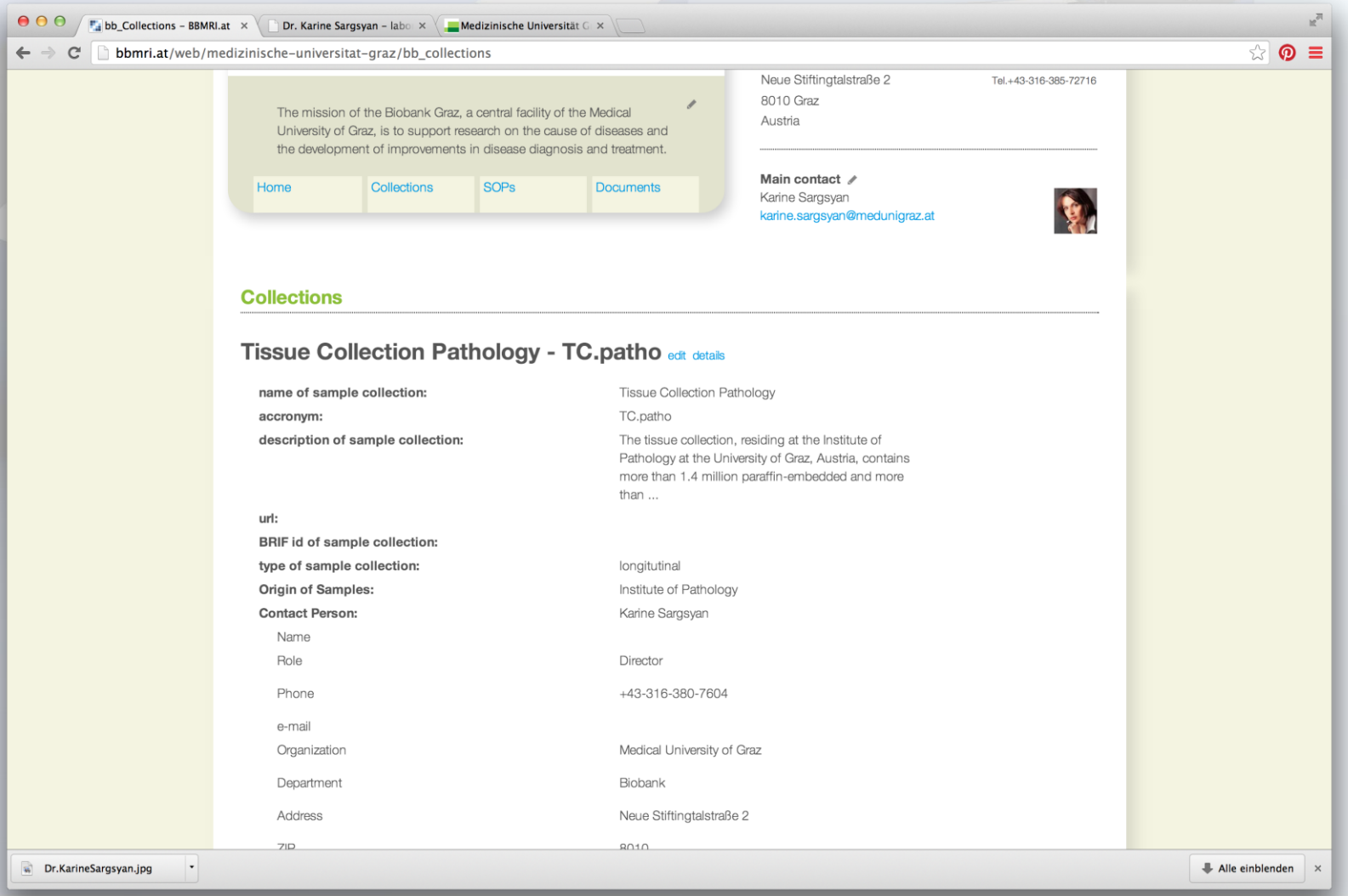

Current ID-Card Portal

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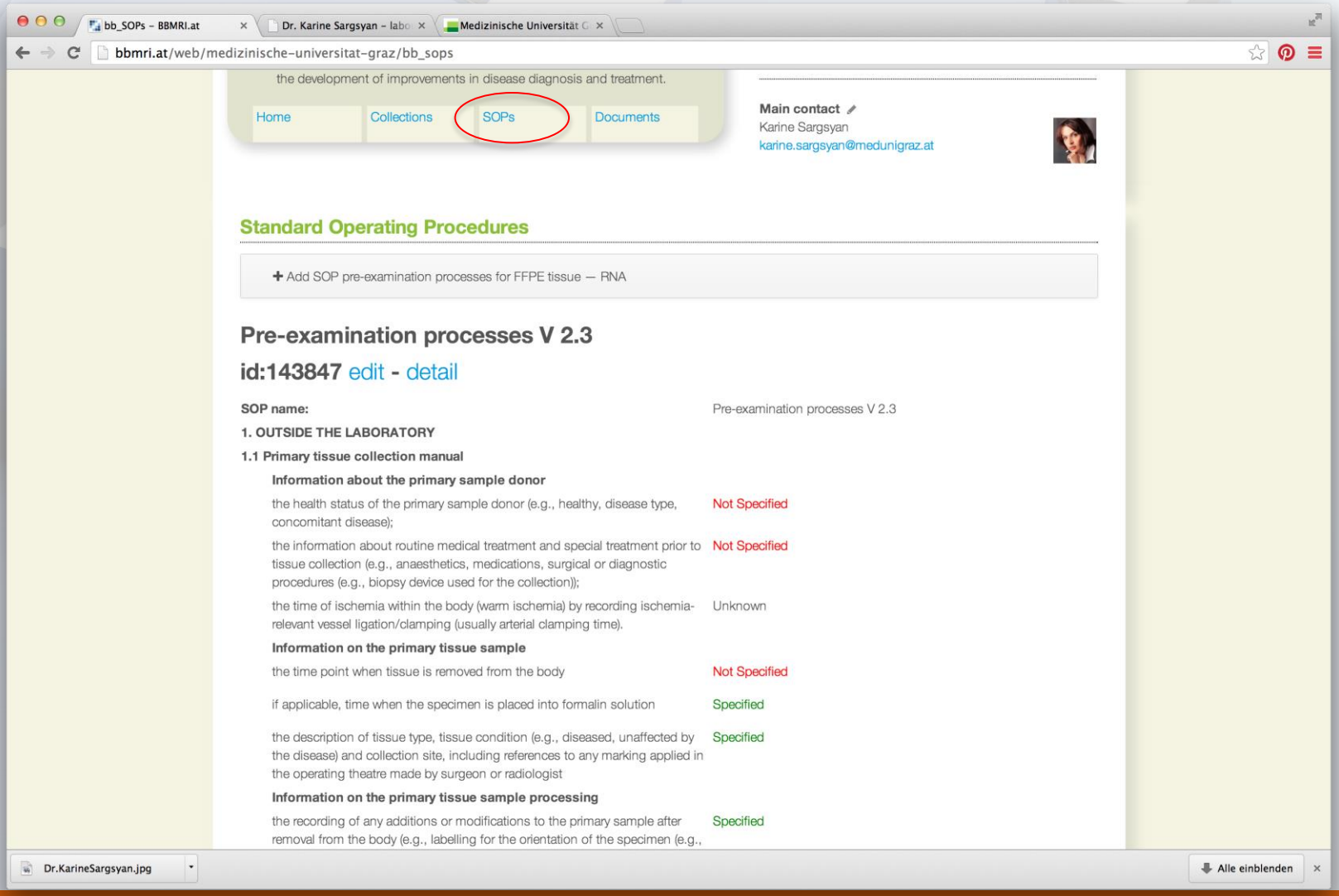
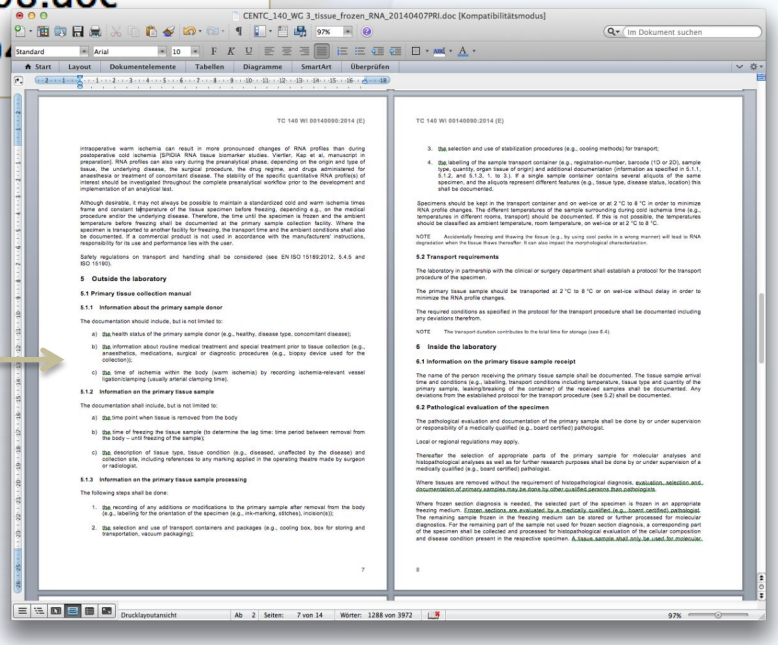


SOP-Mapping

- CEN Standards

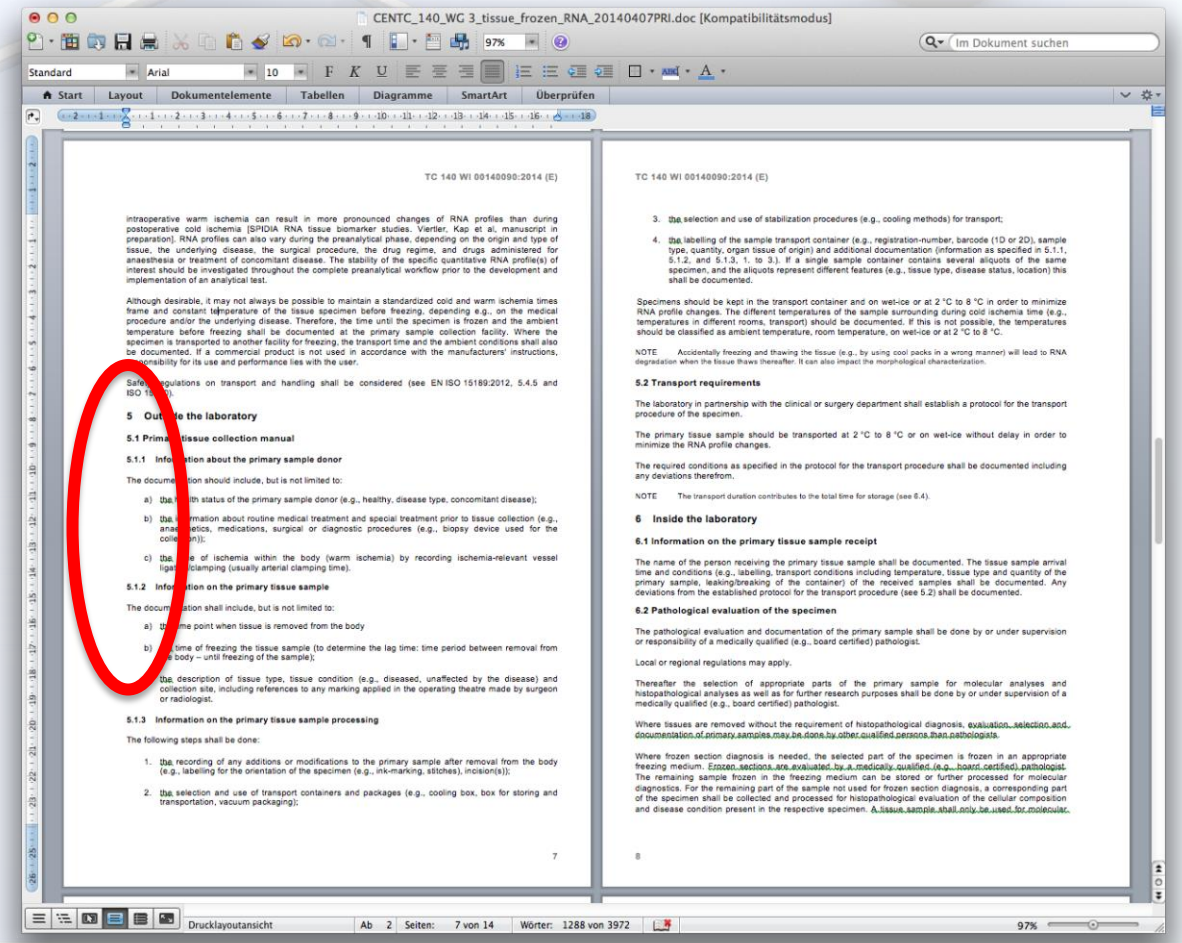
CENTC_140_tissue_FFPE-protein_LL_20140408.doc
CENTC_140_tissue_protein-cryo_20140408.doc
CENTC_140_WG 3_blood_cellular RNA_20140206.doc
CENTC_140_WG 3_blood_genomic DNA_20140206.doc
CENTC_140_WG 3_tissue_FFPE_DNA_20140206.doc
CENTC_140_WG 3_tissue_FFPE_RNA_20140408.doc
CENTC_140_WG 3_tissue_frozen_RNA_20140



SOP-Mapping

- ENTC_140_WG 3_tissue_frozen_RNA_

Headings



SOP-Mapping

- Heading / Structure of the CEN Standard

Table 1 – SOP information categories: pre-examination processes for frozen tissue to RNA

Documentation /Information Category	Attribute Category
Information about the primary sample donor	NS/GPS/GS
• the health status of the primary sample donor (e.g., healthy, disease type, concomitant disease);	NS/DFS
• the information about routine medical treatment and special treatment prior to tissue collection (e.g., anaesthetics, medications, surgical or diagnostic procedures (e.g., biopsy device used for the collection));	NS/DFS
• the time of ischemia within the body (warm ischemia) by recording ischemia-relevant vessel ligation/clamping (usually arterial clamping time).	NS/DFS
Information on the primary tissue sample	NS/GPS/GS
• the time point when tissue is removed from the body	NS/DFS
• the time of freezing the tissue sample (to determine the lag time: time period between removal from the body – until freezing of the sample);	NS/DFS
• the description of tissue type, tissue condition (e.g., diseased, unaffected by the disease) and collection site, including references to any marking applied in the operating theatre made by surgeon or radiologist.	NS/DFS
Information on the primary tissue sample processing	NS/GPS/GS
• the recording of any additions or modifications to the primary sample after removal from the body (e.g., labelling for the orientation of the specimen (e.g., ink-marking, stitches), incision(s));	
• the selection and use of transport containers and packages (e.g., cooling box, box for storing and transportation, vacuum packaging);	NS/DFS
• the selection and use of stabilization procedures (e.g., cooling methods) for transport;	NS/DFS
• the labelling of the sample transport container (e.g., registration-number, barcode (1D or 2D), sample type, quantity, organ tissue of origin) and additional documentation	NS/DFS
• If a single sample container contains several aliquots of the same specimen, and the aliquots represent different features (e.g., tissue type, disease status, location) this shall be documented.	NS/DFS
Transport requirements	NS/GPS/GS
• The laboratory in partnership with the clinical or surgery department shall establish a protocol for the transport procedure of the specimen.	NS/DFS
• The primary tissue sample should be transported at 2 °C to 8 °C or on wet-ice without delay in order to minimize the RNA profile changes.	NS/DFS/VS
• The required conditions as specified in the protocol for the transport procedure shall be documented including any deviations therefrom	NS/DFS
Information on the primary tissue sample receipt	NS/GPS/GS
• The name of the person receiving the primary tissue sample shall be documented.	NS/DFS
• The tissue sample arrival time and conditions (e.g., labelling, transport conditions including temperature, tissue type and	NS/DFS
quantity of the primary sample, leaking/breaking of the container) of the received samples shall be documented.	
• Any deviations from the established protocol for the transport procedure shall be documented.	NS/DFS
Pathological evaluation of the specimen	NS/GPS/GS
• The pathological evaluation and documentation of the primary sample shall be done by or under supervision or responsibility of a medically qualified (e.g., board certified) pathologist.	NS/DFS
• Thereafter the selection of appropriate parts of the primary sample for molecular analyses and histopathological analyses as well as for further research purposes shall be done by or under supervision of a medically qualified (e.g., board certified) pathologist.	NS/DFS
• Where tissues are removed without the requirement of histopathological diagnosis, evaluation, selection and documentation of primary samples may be done by other qualified persons than pathologists.	NS/DFS
• Where frozen section diagnosis is needed, the selected part of the specimen is frozen in an appropriate freezing medium. Frozen sections are evaluated by a medically qualified (e.g., board certified) pathologist. The remaining sample frozen in the freezing medium can be stored or further processed for molecular diagnostics. For the remaining part of the sample not used for frozen section diagnosis, a corresponding part of the specimen shall be collected and processed for histopathological evaluation of the cellular composition and disease condition present in the respective specimen.	NS/DFS
• A tissue sample shall only be used for molecular testing after histopathological characterization of its cellular composition, disease condition and preservation status by a medically qualified (e.g., board certified) pathologist.	NS/DFS
Cryo-preservation of the specimen	NS/GPS/GS
• the recording of freezing procedure (e.g., freezing in liquid nitrogen, snap-freezing in isopentane cooled by liquid nitrogen or dry ice, freezing in an appropriate freezing medium, freezing with controlled cooling rate);	NS/DFS
• the recording of freezing time point;	NS/DFS
• the tissue size determines the size of the container and the sample should not exceed 1 cm in one dimension;	NS/DFS/VS
• the selection of the sample container for cryo-storage	NS/DFS
• the labelling shall be suitable for the respective frozen storage conditions	NS/DFS
• the labelling of the cryo-storage container shall contain the minimum information of (a) the patient ID, which can be in the form of a code;	NS/DFS
• the basic information on e.g., the tissue type, tissue and disease condition such as affected (e.g., tumor) or unaffected, unless a sample tracking system can supply this information coupled to the identification of the sample used in	
Storage requirements	NS/GPS/GS
• The constant temperature shall be below -70 °C. Systems monitoring the temperature should be used.	NS/DFS/VS

SOP-Mapping

- **Description of groups of attributes (sections)**

  NS=non specified

  GPS=group partialy, specified

  GS=group specified.

- **Description of items within groups**

  NS= non specified

  DFS=data field given

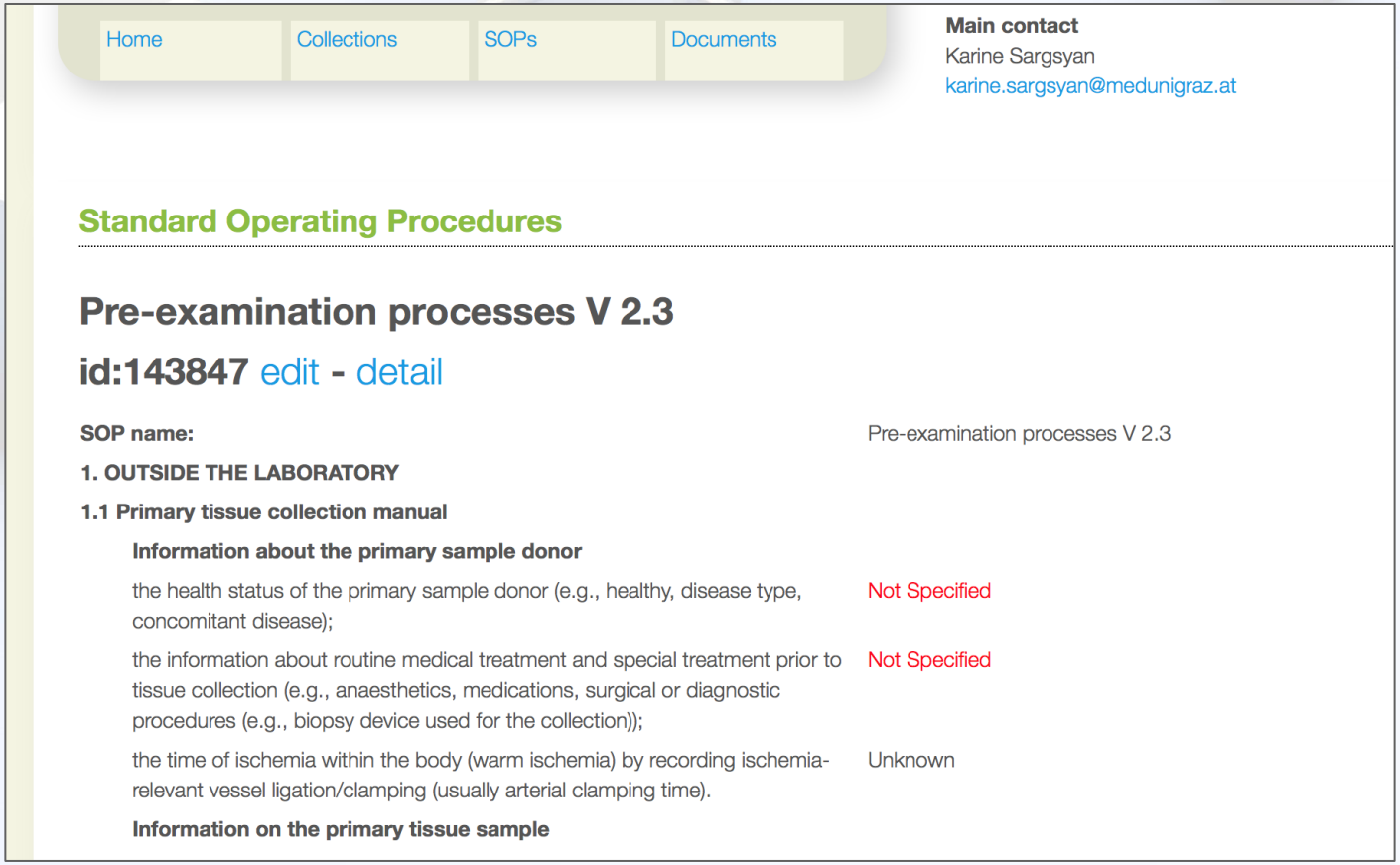
  VS=value specified

Table 1 – SOP information categories: pre-examination processes for frozen tissue to RNA

Documentation /Information Category	Attribute Category
Information about the primary sample donor	NS/GPS/GS
• the health status of the primary sample donor (e.g., healthy, disease type, concomitant disease);	NS/DFS
• the information about routine medical treatment and special treatment prior to tissue collection (e.g., anaesthetics, medications, surgical or diagnostic procedures (e.g., biopsy device used for the collection));	NS/DFS
• the time of ischemia within the body (warm ischemia) by recording ischemia-relevant vessel ligation/clamping (usually arterial clamping time).	NS/DFS
Information on the primary tissue sample	NS/GPS/GS
• the time point when tissue is removed from the body	NS/DFS
• the time of freezing the tissue sample (to determine the lag	NS/DFS

SOP-Mapping within ID-Card

- Describe your SOPs within ID-card portal



Home | Collections | SOPs | Documents

Main contact
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Standard Operating Procedures

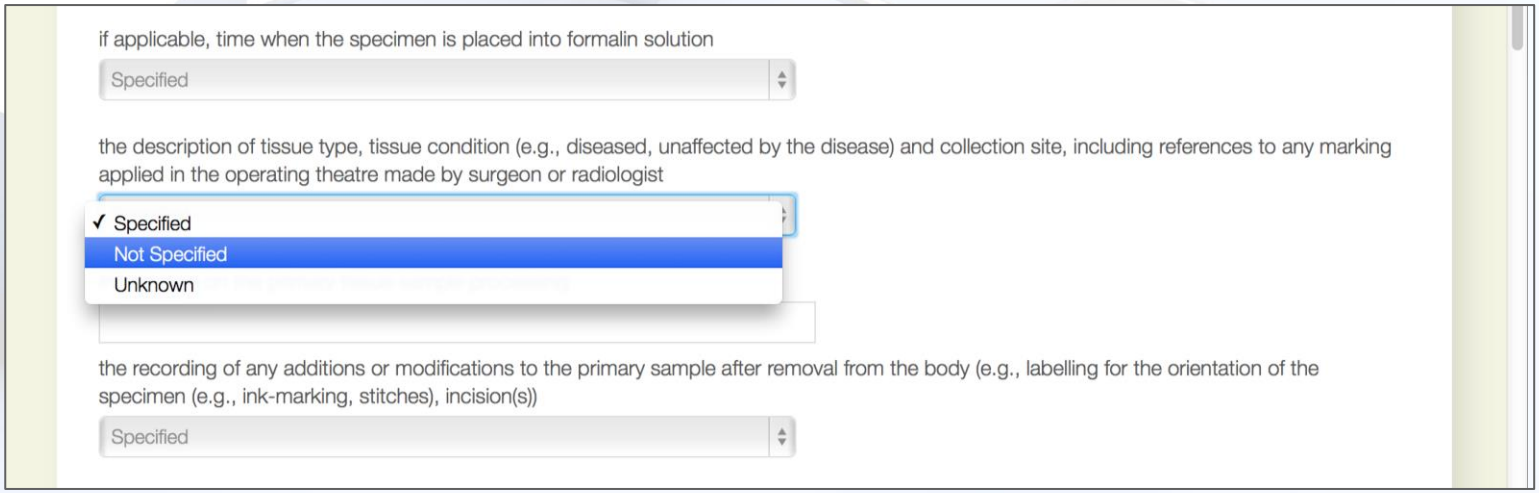
Pre-examination processes V 2.3

id:143847 edit - detail

SOP name:	Pre-examination processes V 2.3
1. OUTSIDE THE LABORATORY	
1.1 Primary tissue collection manual	
Information about the primary sample donor	
the health status of the primary sample donor (e.g., healthy, disease type, concomitant disease);	Not Specified
the information about routine medical treatment and special treatment prior to tissue collection (e.g., anaesthetics, medications, surgical or diagnostic procedures (e.g., biopsy device used for the collection));	Not Specified
the time of ischemia within the body (warm ischemia) by recording ischemia-relevant vessel ligation/clamping (usually arterial clamping time).	Unknown
Information on the primary tissue sample	

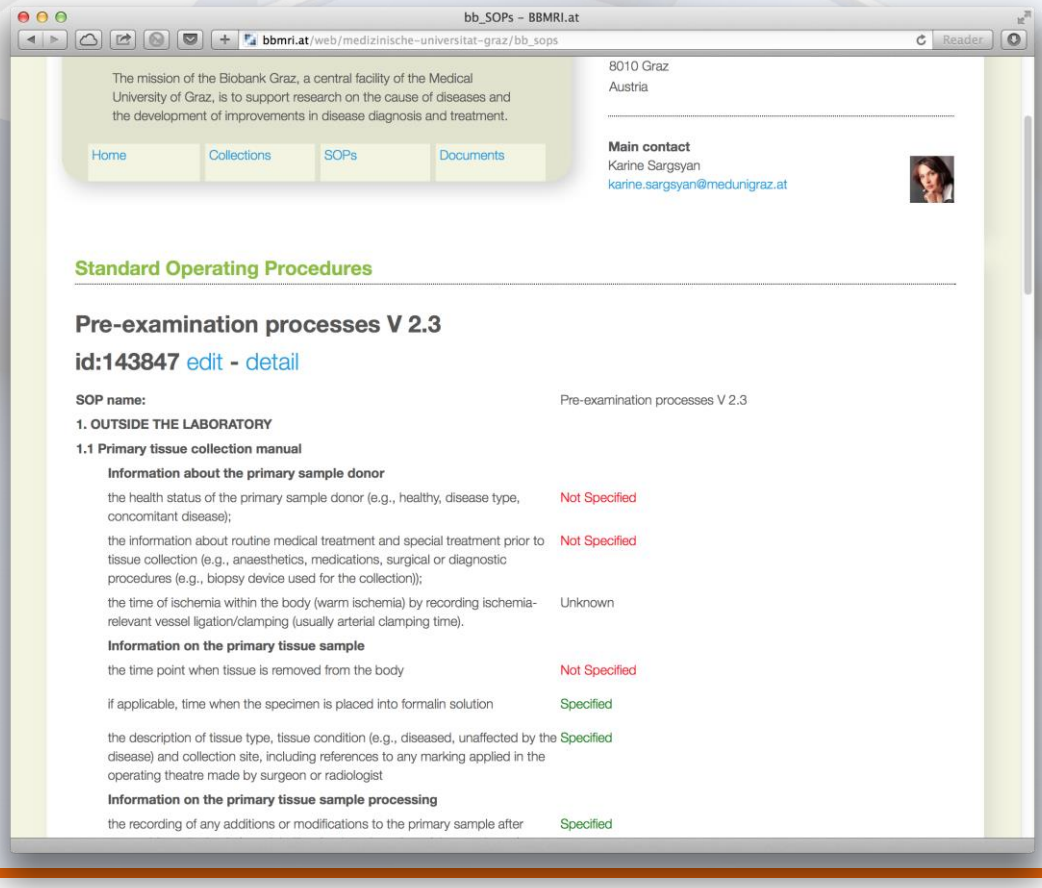
SOP-Mapping within ID-Card

- (Easy) editing by biobank editors



SOP-Mapping within ID-Card

- Beta Test ongoing within the RD-Connect ID card and the BBRMI.at Portal
- SOP mapping can be connected to collections / sample descriptions



SOP-Mapping

- Get an overview of the structure of the SOPs used (what is defined)
- Compare Collections on the collection process
- Quality improvement indicator for a biobank/network

Next Steps

- Extend the information collected on values (licensing?)
- Create SOPs out of the entered data
- Compare SOPs structured in the same way

THANK YOU!

- Peter, Marco, Lucia, Peter, Moris, David, Roxanna (WP3)
- Sabina, Paola, Gaelle, Estrella, Domenica, Filippo, Luca (WP2)
- Horst (BBMRI)

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