

EUROPE BIOBANK WEEK

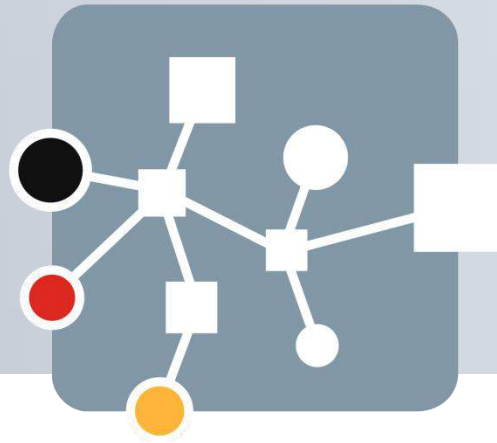
SEPTEMBER 13-16, 2016
VIENNA - AUSTRIA

Sabrina Schmitt: "German Biobank Node's concept for quality management"



www.europebiobankweek.eu





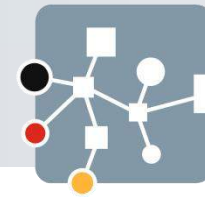
German
Biobank Node
bbmri.de

German Biobank Node's concept for quality management

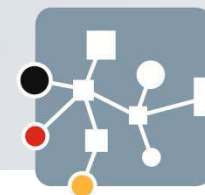
S. Schmitt

K.-F. Becker, B. Meinung, E. Herpel, J. Slotta-Huspenina

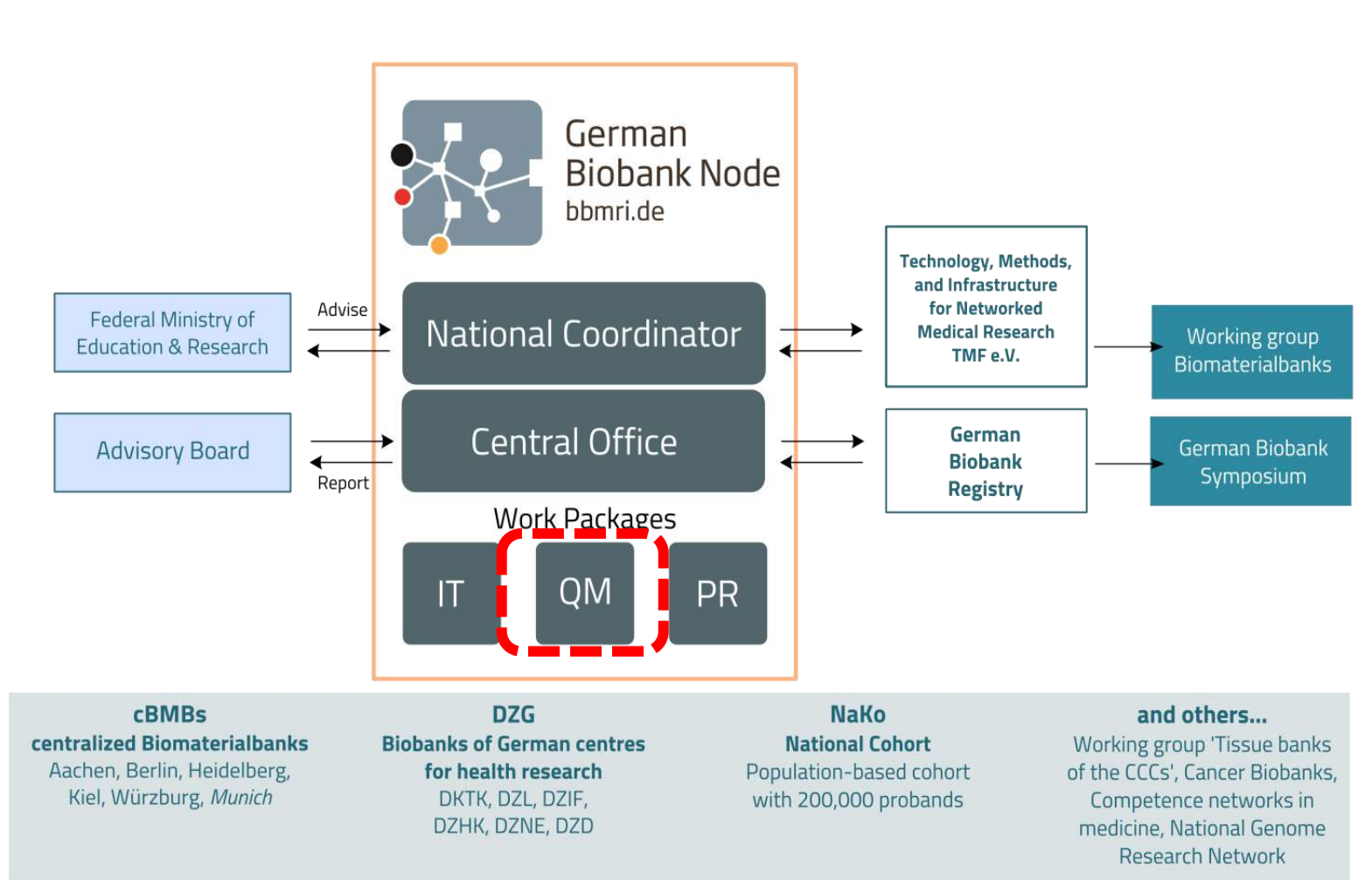
Sep-14-2016, European Biobank Week, Vienna



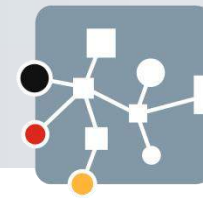
- 2013, national node partner of BBMRI-ERIC
- central contact and exchange platform for the German Biobank community - for researchers, for politics, media, representatives of patients, industry and funding institutions.
- **aims and activities**
 - optimize networking of national biobanks
 - facilitate exchanges of experience between biobanks
 - **the development of standards for quality assurance**
 - the elaboration of an IT concept for the exchange of samples and data
 - inform the public about biobank activities



Structure



QM-WP3: “Biobank Quality Management for body fluids and tissues”



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Participating Biobanks

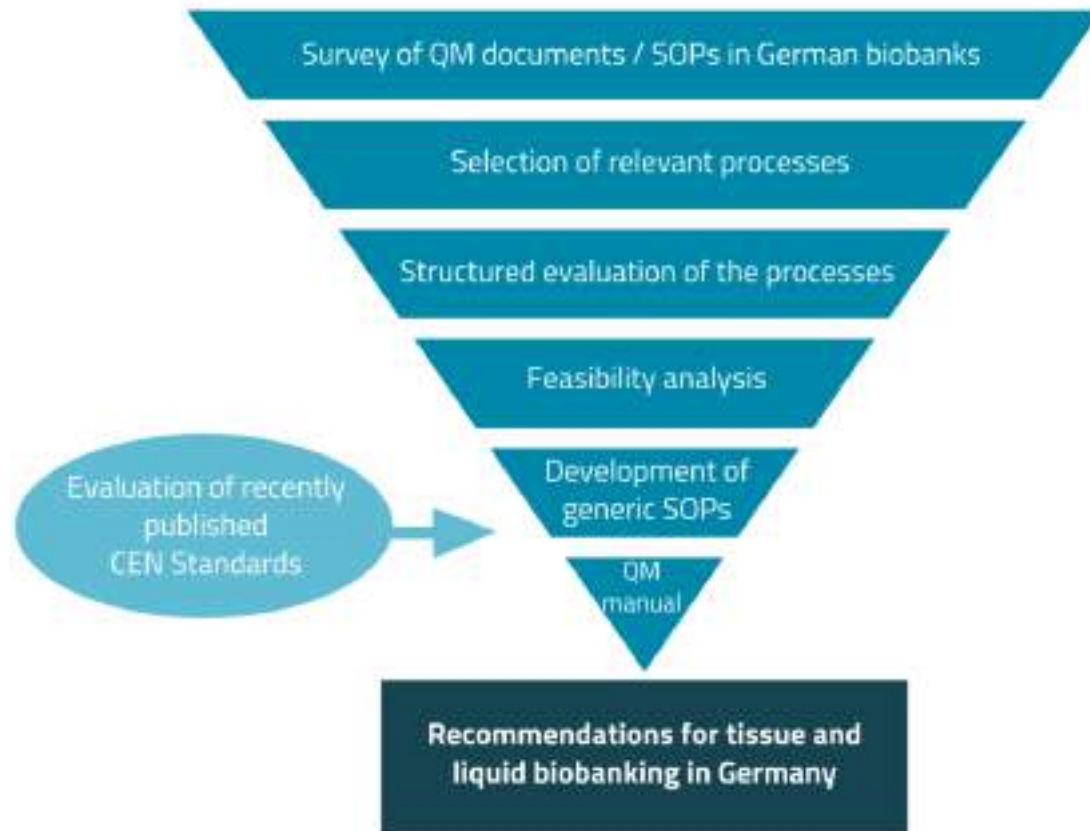
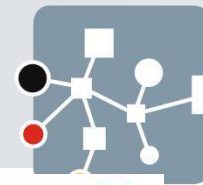
- Tissue only
- Liquid only
- Tissue & liquid

Coordination

Liquid: PD Dr. Dr. Michael Kiehntopf, Jena
Bettina Meinung, Jena

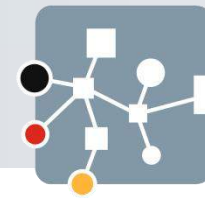
Tissue: Prof. P. Schirmacher, Heidelberg
PD Dr. E. Herpel, Heidelberg
Dr. S. Schmitt, Heidelberg
Dr. J. Slotta-Huspenina, Munich
Prof. Dr. K.-F. Becker, Munich



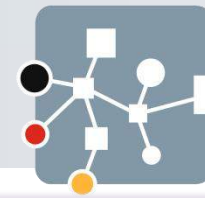


- Large, representative German biobanks were invited to
 - participate and provided **SOPs**
 - fill out a **comprehensive questionnaire**
- Core processes and parameters to be described were determined at joint workshops

The Questionnaire



Requirements (according to DIN EN ISO 17025, DIN EN ISO 17020, DIN ISO 9001)	Fulfilment [%]
Definition of the biobank as an organisation , legal questions, responsibilities, impartiality, fulfilment of ISO 9001 mandatory procedures, already accredited/certified biobank?	75%
Fulfilment of regulations and legal requirements , existing project management, complaints and objections described, confidentiality guaranteed?	77%
Ethical regulations fulfilled?	100%
Subcontracting defined?	75%
Procedures for validation established?	60%
Is there an inspection equipment monitoring/maintenance /? Emergency plans? Floor plans, access regulations?	85%
Are all processes and procedures described and being documented as well as monitored (in detail: preanalytical processes, sample collection, storage, processing, transfer and transport, project management ..)? Is there training for employees?	75%
Organisation of document and records management ?	70%
System of quality control and quality assurance ?	75%

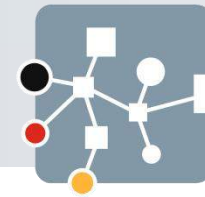


Identification of relevant processes and key parameters in 3 joint workshops with the participating biobanks

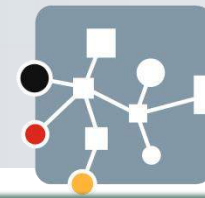


Photo: Ida Steier

The Process Matrix



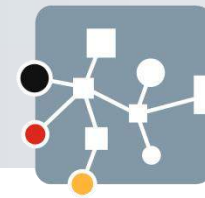
Management processes	Core processes	Supporting processes
Policy and strategy	Sample management	Equipment management
Ethics	Sample collection	Quality management
Organisation	Sample drawing	Quality assurance (internal, external)
Provision of resources	Sample transport	Risk management
Contract administration	Sample receipt	Security management
Human resource management	Registration	Documentation
Procurement	Sample processing	Data backup
Communication	Sample storage	Control of documents and records
Data protection	Storage	
	Removal	
	<i>Destruction</i>	
	<i>Ordering of samples</i>	
	Data management	
	Project management	



Generation of core process descriptions and SOPs covering
relevant standards
as well as the CEN technical specifications
„Core team“ Jena/Heidelberg/Munich



Generic recommendations and templates for core processes



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Name der Biobank	Anforderung und	Leitung der Biobank XXX
Entf. Logo	Abgabe von Proben	Verfahrensweisung

Nicht verwendetes Material oder verwendungsfähiges Material ist nach Ende der Untersuchungen gemäß geltender Vorgaben zu entsorgen.

Der gesamte Prozess muss bis zur Probenübernahme dokumentiert werden.

Während des gesamten Arbeitsablaufs müssen Vorsichtsmaßnahmen zur Vermeidung von Kreuzkontaminationen zwischen unterschiedlichen Proben getroffen werden.

7. Projektdokumentation

Die Projektdokumentation erfolgt fortlaufend. Basisdokument ist der jeweils zu verwendende Projektantrag. Projektbezogen erhalten die Nutzer der Biobank folgende Unterlagen:

- Anknüpfungsf formular
- Empfangsbestätigung/Versandbewertung
- Bestätigung über angenommenen Antrag
- Probenversandlisten/Übergabeprotokoll
- QC-Kontrolle

Die Dokumentation der Probenlagerung erfolgt elektronisch

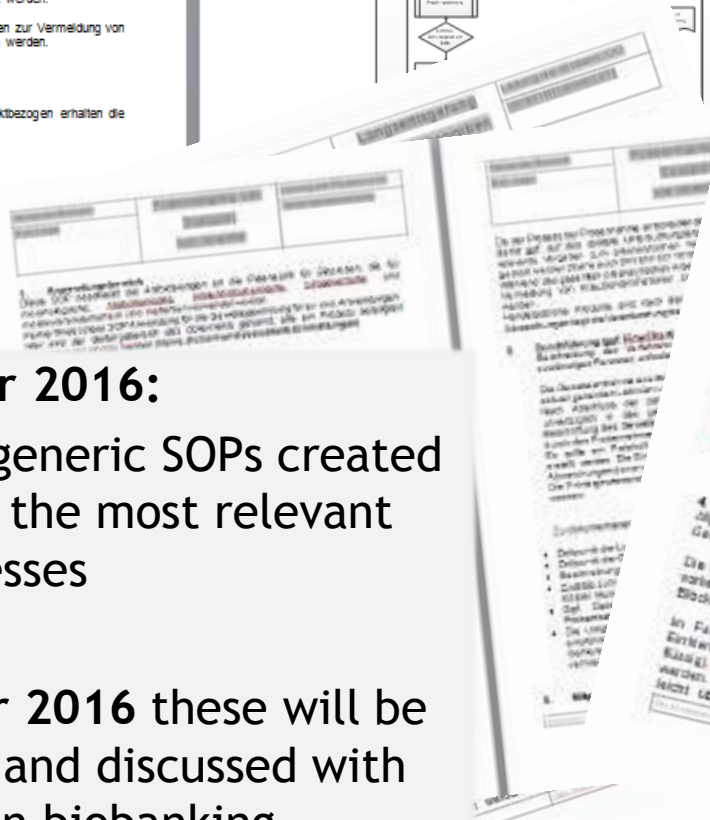
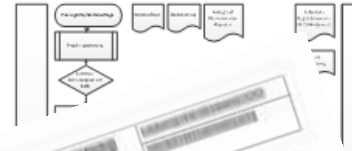
Die Nutzermanagementmatrix dient dem Gesamtüberblick über Einrichtungen/ Kliniken und dem Anbindungsstatus der einzelnen

Die Studienmatrix dient dem Gesamtüberblick der eingelagerten **inkl. Studienbezogenen** Lagervolumen, Ein- und Ausgang

- Proben und S
- Forschungsz
- Probenausg
- re-sultierende
- Projekt- und L

Anhand der kontinuierlich Abgleich.
Die Kommunikation der Regelmäßigkeit werden die E Biobank ein.

Name der Biobank	Anforderung und	Leitung der Biobank XXX
Entf. Logo	Abgabe von Proben	Verfahrensweisung



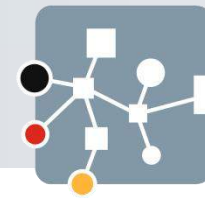
September 2016:

So far, 16 generic SOPs created that cover the most relevant core processes

In October 2016 these will be presented and discussed with the German biobanking community

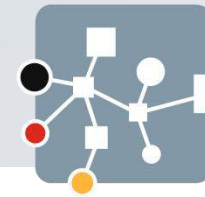
Formular





Release of „generic handbook“ template
end of 2016 - also covering leadership and
supporting processes

- available via GBN
- Results will be published in 2017
- Will have to be regularly updated
(ISO/TC 276 - biobanking standard) and
revised



Thank You

German Biobank Node
Prof. Dr. Michael Hummel
Dr. Cornelia Rufenach

PD Dr. Dr. Michael Kiehntopf, Jena,
Bettina Meinung, Jena
Prof. P. Schirmacher, Heidelberg
PD Dr. E. Herpel, Heidelberg
Dr. J. Slotta-Huspenina, Munich
Prof. Dr. K.-F. Becker, Munich