BONEBANK – Data Management
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SOVENTEC – THE COMPANY

- soventec GmbH is part of the BONEBANK consortium
- software engineering company and IT service provider
- specialised in medical applications
- certified according to ISO 13485 since 2010
- several national and international projects meeting the high quality demands of the medical device regulations (ISO 13485, ISO 14971, ISO 62304)

How we work
- Software development team uses agile methodologies and tools to continuously incorporate customer feedback, quality assurance and any other change of requirements
- Good experiences in working agile **and** according to strict regulations

PROJECTS – CUSTOMERS

- Laboratory automation projects – development of software components for devices, device integration, web applications

- Software for medical devices

- Software Frontend for complex active implantable devices

- Data management with our own software **Lab OS®** (like BONEBANK)
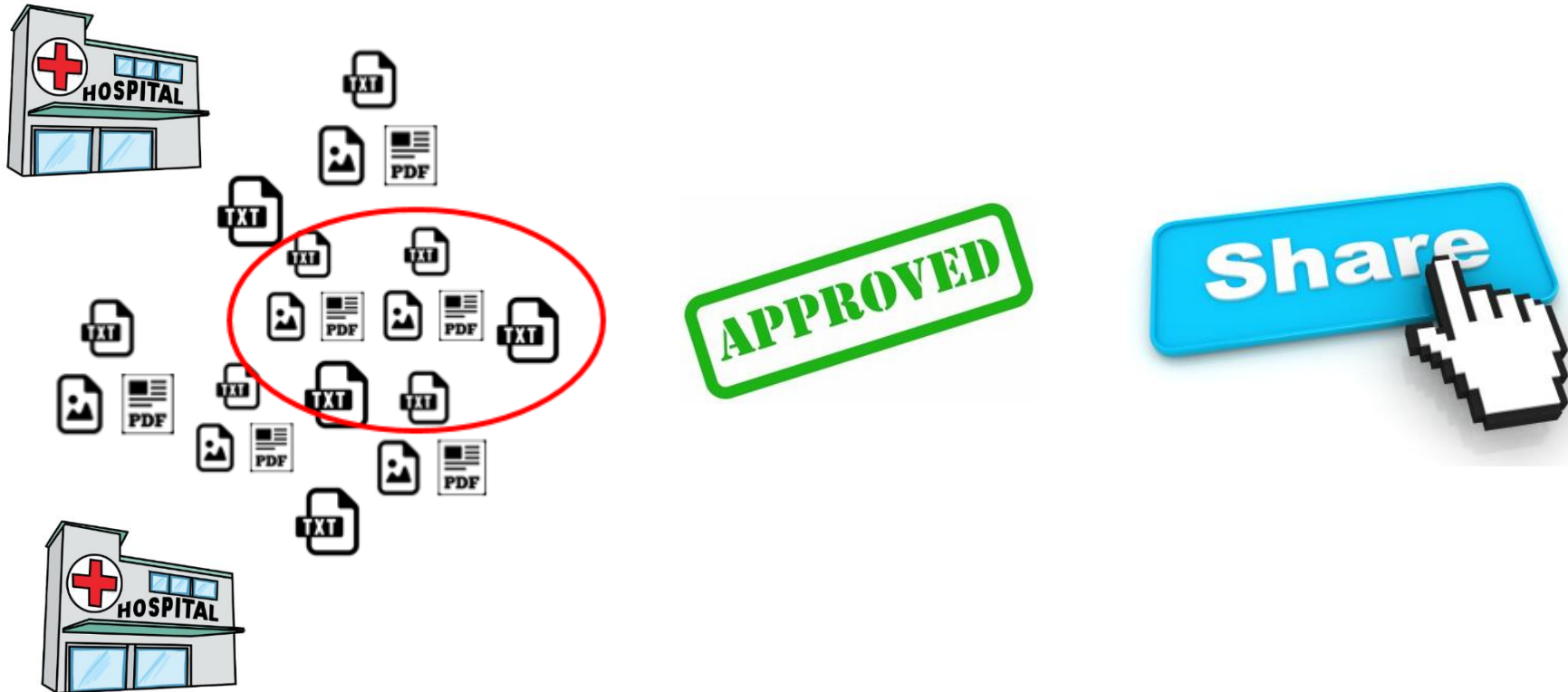
THE BONEBANK CHALLENGE

sample data in local IT system, highly regulated

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- synchronizing SOPs
- treating the samples identically
- giving the crossborder partner access to data of fresh and cryopreserved material
- data management has to meet hospital regulations, ethical regulations, national laws
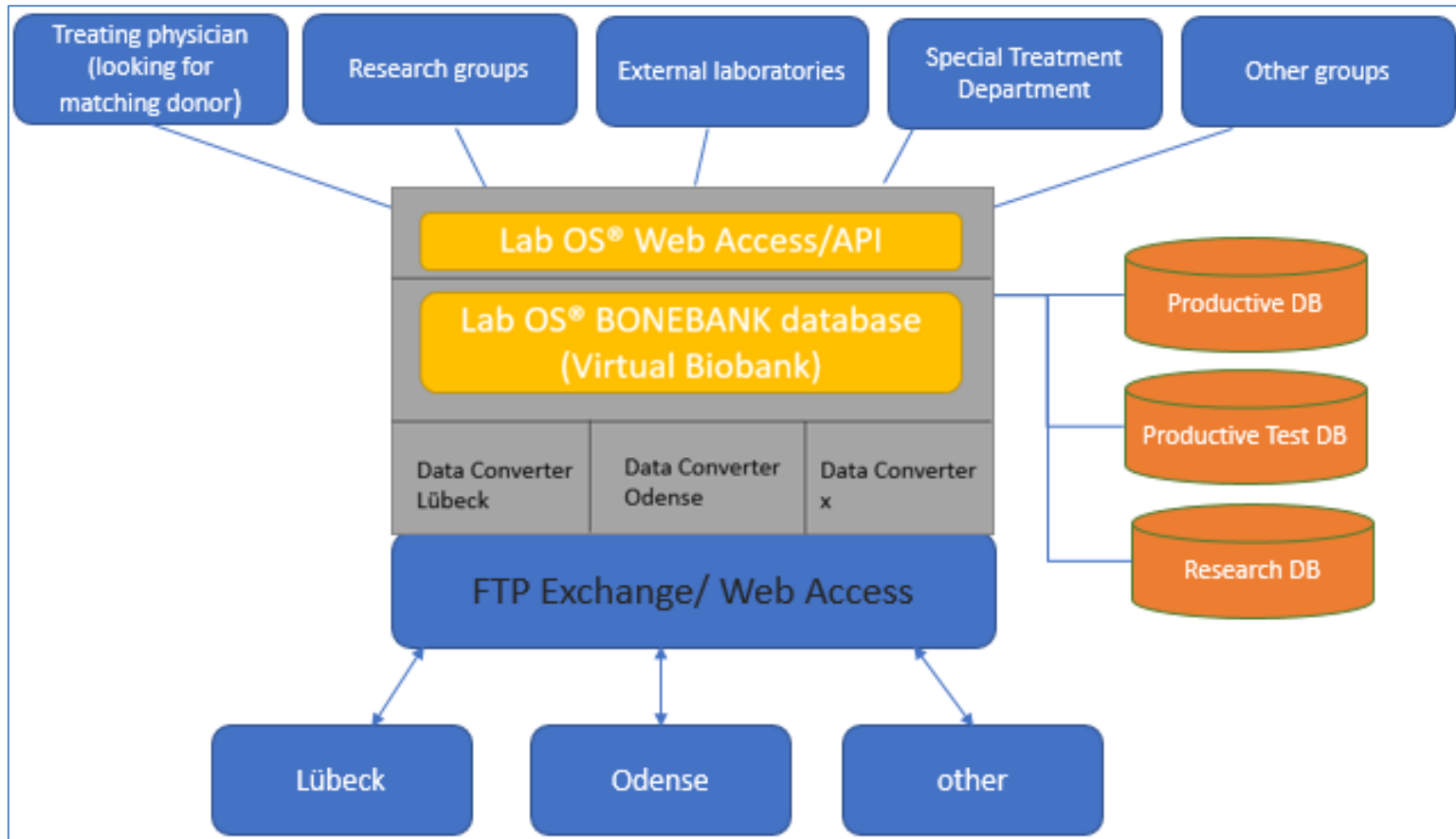
DATAMANAGEMENT – Working with shared sensitive data
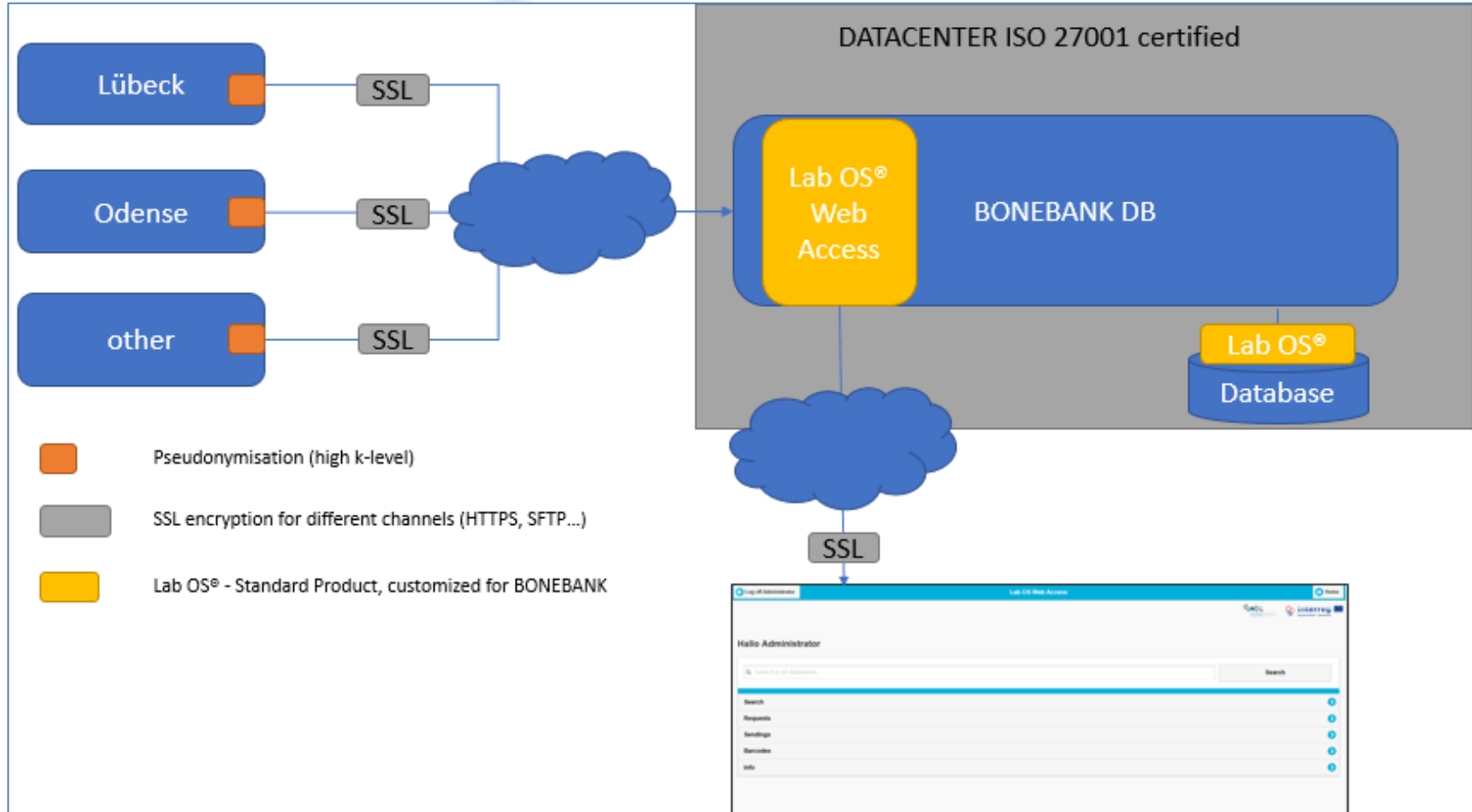
DATAMANAGEMENT – Working with shared sensitive data

Technical solution

➢ soventec uses its software **Lab OS®** as potent IT backbone

➢ **Lab OS®** is a software platform to administer samples and sample related information

➢ suitable for customer specific applications due to its high modularity and scalability

➢ client server database software solution with safety and security features

➢ powerful user access management with configurable access layer

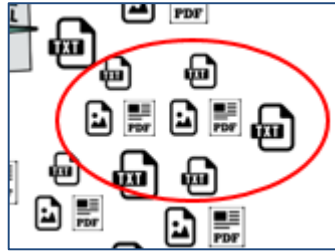➢ provides web services for sample querying, requests and management of shared data

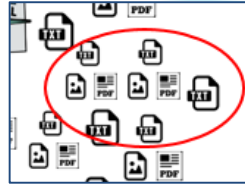# Technical solution

Technical solution

Content discussion

- Hospitals have a lot of data concerning sample material and patients

- What information **can** be shared?
- What information is **needed** to characterise samples adequatly?

- Who will search for samples? What are the characteristics they need?

- In BONEBANK it was a long process to define this
- All partners agreed on a **common data set**
- soventec generated a data template that can be added to all shared samples
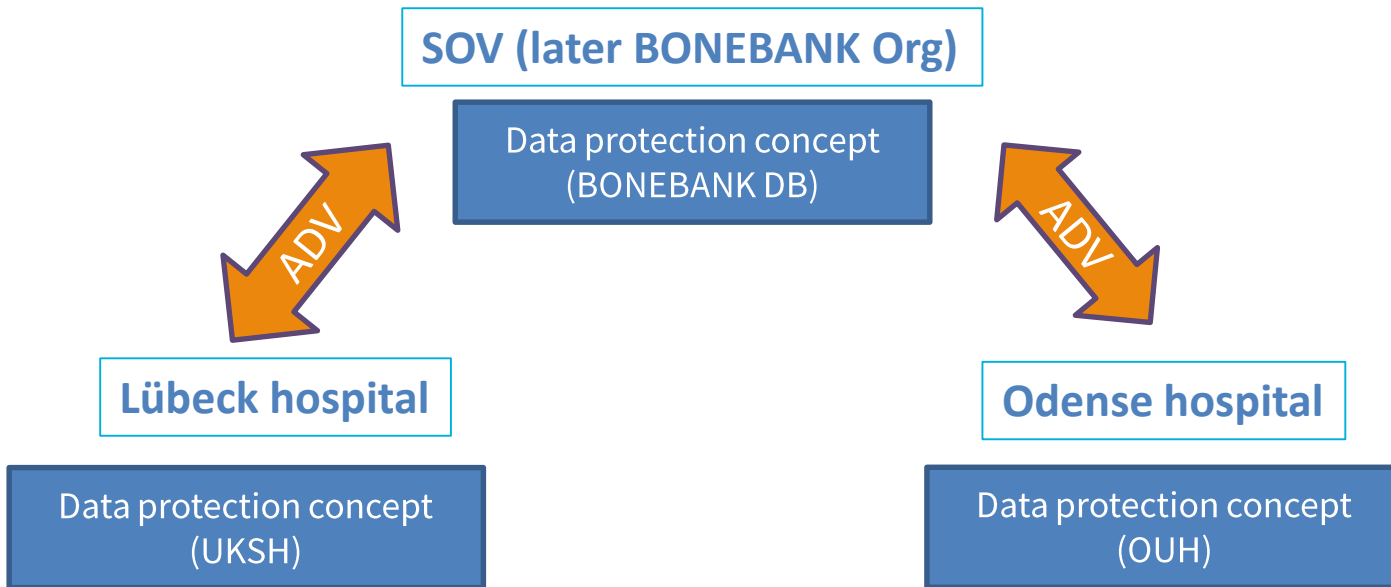
Common parameter set

Patient	
Age Range	
Gender:	
Hb, when samples was taken (g/dl OR mmol) :	
Leucocytes (cells/microliter) :	
Operation	
Place Sample Withdrawal:	
Diagnosis (ICD 10):	
Treatment SKS:	
Treatment OPS:	
Harvested Material	
Sample	
Sample type	
Storage Temperature	
Storage Temperature / °C	
Sample Location	
Hospital:	
Biobank:	
Contact:	

Different treatment coding systems in Denmark/Germany
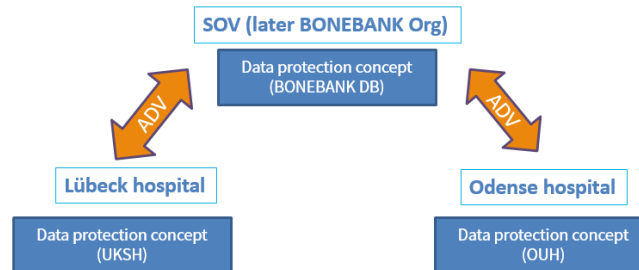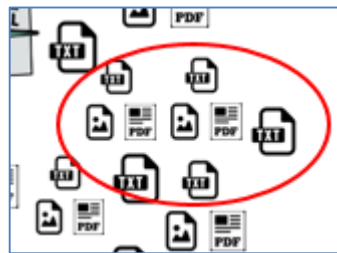(OPS Codes in Lübeck/Germany ⇔ SKS Codes in Danmark)

Ethical/ Legal aspects

- ethic approval needed
- Data security and responsibility have to be garanteed
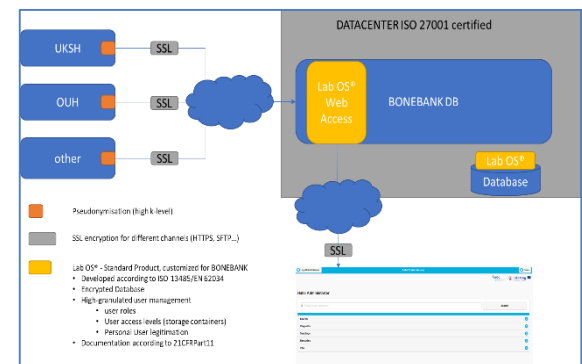- Contracts have to be concluded

SOV (later BONEBANK Org)

Data protection concept
(BONEBANK DB)

ADV

ADV

Lübeck hospital

Data protection concept
(UKSH)

Odense hospital

Data protection concept
(OUH)

ADV: Auftragsdatenverarbeitungsvertrag
(data processing agreement)

Data Management – Working with shared data

Find further information
www.soventec.com
http://labos.soventec.de

Thank you!

Harvesting of bone material

Separation of bone stem cells

Frozen storage in the BoneBank

Cultivation of the bone stem cells

Injection in the bone defect

Healing of the bone defect