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Translational Platform HIV – Expedited Research from Bench to Bedside and Back

J. J. Vehreschild[1], B. Franke[1], S. Heinen[1], B. Shrestha[1], B. Gunsenheimer-Bartmeyer[2], G. Behrens[3], J. Bogner[4], J. Rockstroh[5], J. van Lunzen[6], G. Kräusslich[7], G. Fätkenheuer[1]

1) Uniklinik Köln, Köln; 2) Robert-Koch-Institut, Berlin; 3) Medizinische Hochschule Hannover, Hannover; 4) Klinikum der Universität München, München; 5) Medizinische Universitätsklinik I, Bonn; 6) Universitätsklinikum Eppendorf, Hamburg; 7) Universität Heidelberg, Heidelberg
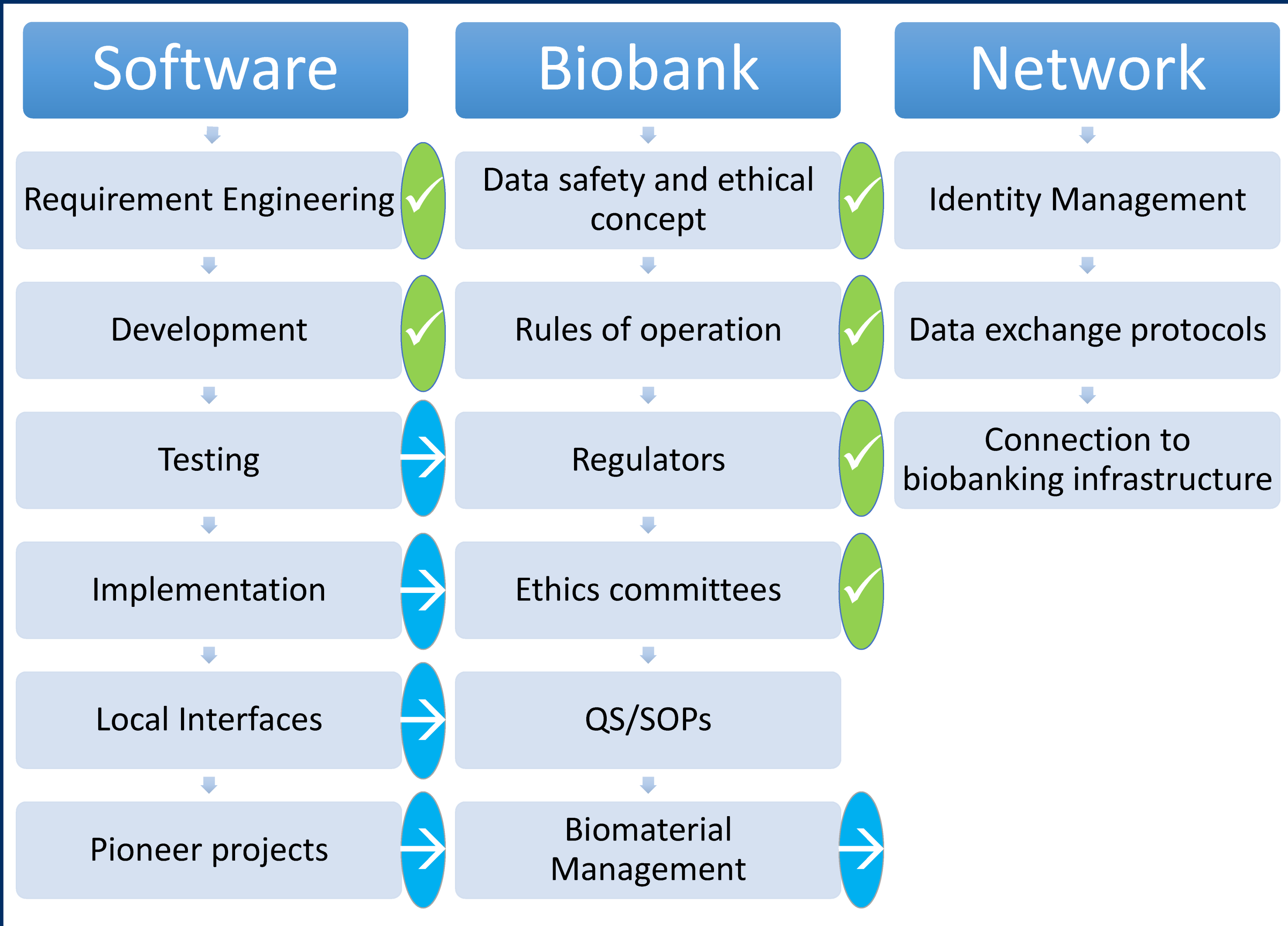
Abstract

Background: All partner sites of the Thematic Translational Unit (TTU) HIV treat HIV patients and gather information in cohorts with local databases and biobanks. While the in-depth information on specific issues (e.g. hepatic or kidney disorders, malignancies) is a strong-hold of these local cohorts, the diversity of the data systems and the lack of coordination limit joint activities. In addition, researchers face increasing demands by regulators and data safety officers for collection and analysis of biological samples with broad patient consent and long-term storage.

Objectives: The HIV Translational Platform will provide an improved infrastructure for cooperation between the existing HIV cohorts of the TTU partner sites. Common technologies and study protocols will allow expedited and comprehensive exchange of information and biomaterial. Prospective biomaterial and patient data collections are the common basis of all scientific projects of the TTU, and this infrastructure intends to promote their overall success by harmonization of efforts and reduction of regulatory overhead.
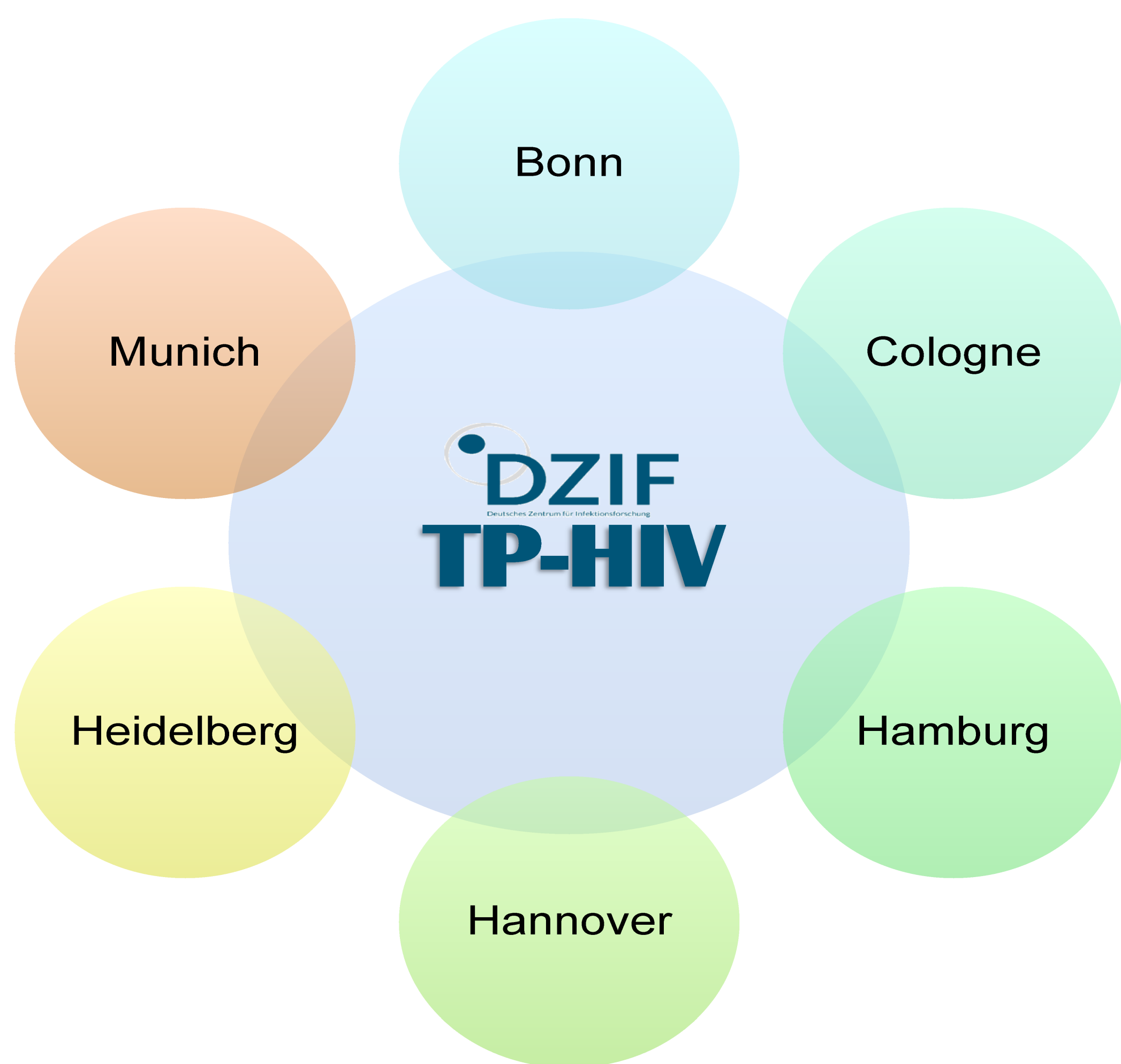
Project: A DZIF research group has been established at the University Hospital of Cologne in July 2013. An interdisciplinary team of software developers and scientists coordinates the HIV Translational Platform and supervises its implementation, which includes providing a data protection concept, ethical and legal clearance documents, as well as biobank accessibility. Furthermore, they provide guidance on ethical and regulatory issues for further HIV research projects to allow rapid implementation of research protocols. This is achieved in close collaboration with DZIF infrastructures, including Biobanking, the Transplantation Cohort and external partners. The Translational Platform will utilize the HIV Observational System (HIObS) provided by the Robert-Koch-Institut, with additional features like connectivity to hospital information systems being developed by the group as part of the DZIF HIV Engaged Research Technology (HEnRY) toolset.

Distinct scientific activities of the platform will focus on the effects and the evidence of European guidelines for treatment of HIV infection and associated disorders, always with a strong emphasis on long-term effects of HIV infection and treatment.

Sites of the TP-HIV

Bonn · Cologne · Hamburg · Hannover · Heidelberg · Munich · DZIF TP-HIV

Introduction

- All sites of the TTU HIV need to share patient data and biomaterials
- Five sites with original patient cohorts, existing databases and biobanks
- Heterogenous databases and cohorts
- Heterogenous IT environment
- Current software at most sites outdated and/or locally developed
- Lack of automatic import from electronic patient records - risk of mistakes, high workload
- Heterogenous study protocols and ethics votes
- Need for a common platform for data and biomaterial exchange
- Need for DZIF-wide epidemiological and experimental research

Software Concept

HIObS
- Demography
- Clinical Data
- Medication
- Virology
- ClinSurv

HEnRY
- Biobanking
- Interfaces
- Resistance data
- Complex user defined data
- HICDEP

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Milestones and Progress thus far

Software	Biobank	Network
Requirement Engineering ✓	Data safety and ethical concept ✓	Identity Management
Development ✓	Rules of operation ✓	Data exchange protocols
Testing →	Regulators ✓	Connection to biobanking infrastructure
Implementation →	Ethics committees ✓	
Local Interfaces →	QS/SOPs	
Pioneer projects →	Biomaterial Management →	

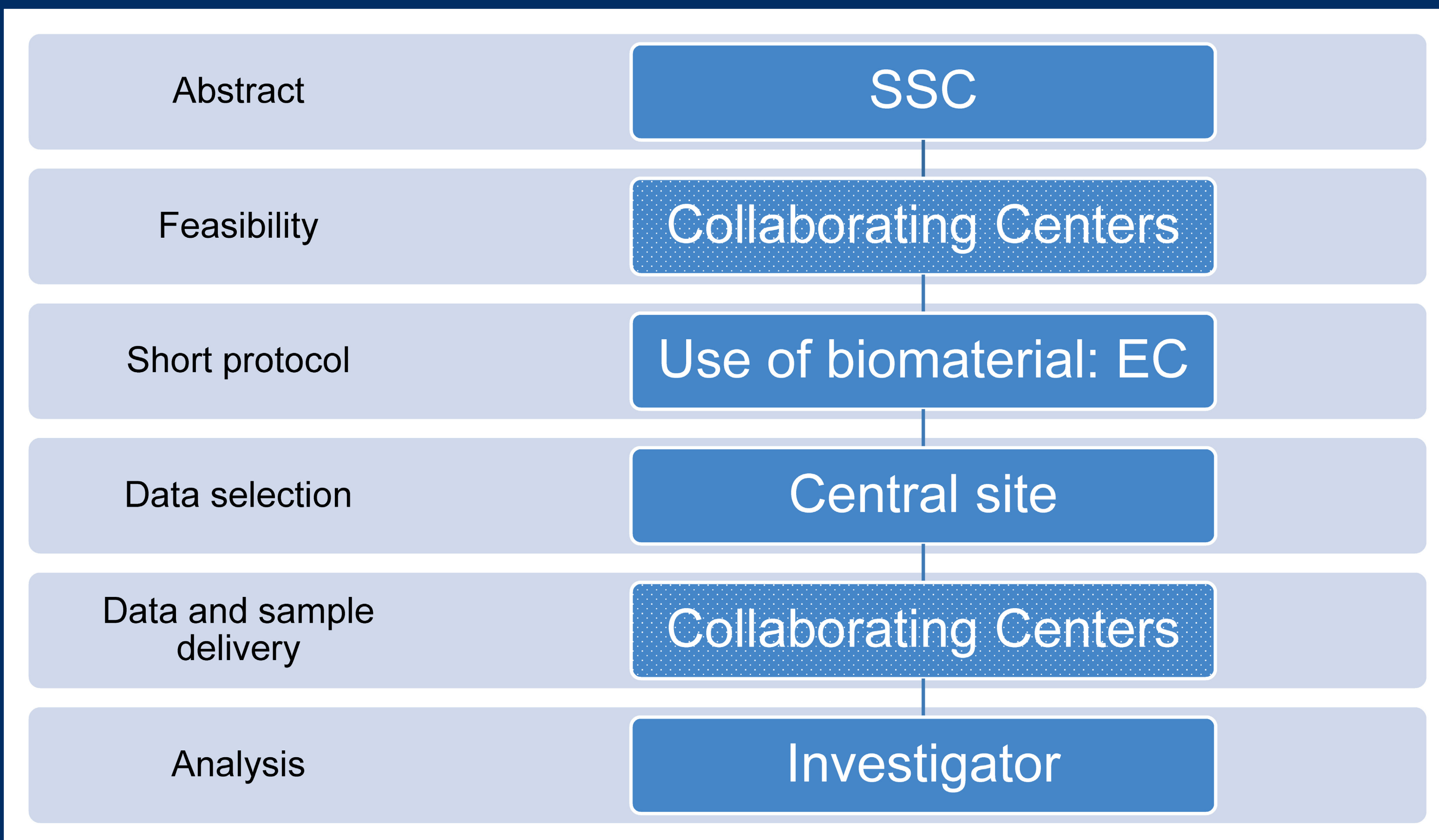## Concept

- Junior research group "Cohorts in HIV infection"
- Cooperation with Robert-Koch-Institut, TTU IIRC, TI Biobanking
- Design of common study protocol and biobanking concept
- Development of unified software platform
- Full service for translational research: feasibility studies, protocol development, ethics committee and regulatory approval, data warehouse, biomaterial exchange, statistical analysis

Workflow

Abstract	SSC
Feasibility	Collaborating Centers
Short protocol	Use of biomaterial: EC
Data selection	Central site
Data and sample delivery	Collaborating Centers
Analysis	Investigator

State of Affairs

- Postive statement from regulatory agency (BfArM)
- Positive votes from ethics committees: Bonn, Cologne, Hannover
- Votes pending from ethics committees: Hamburg, Munich (x2)
- Software (HIObs and HEnRY) feature-complete, currently alpha testing
- Pilot phase Bonn/Cologne in January 2015
- Other centers to follow until July 2015
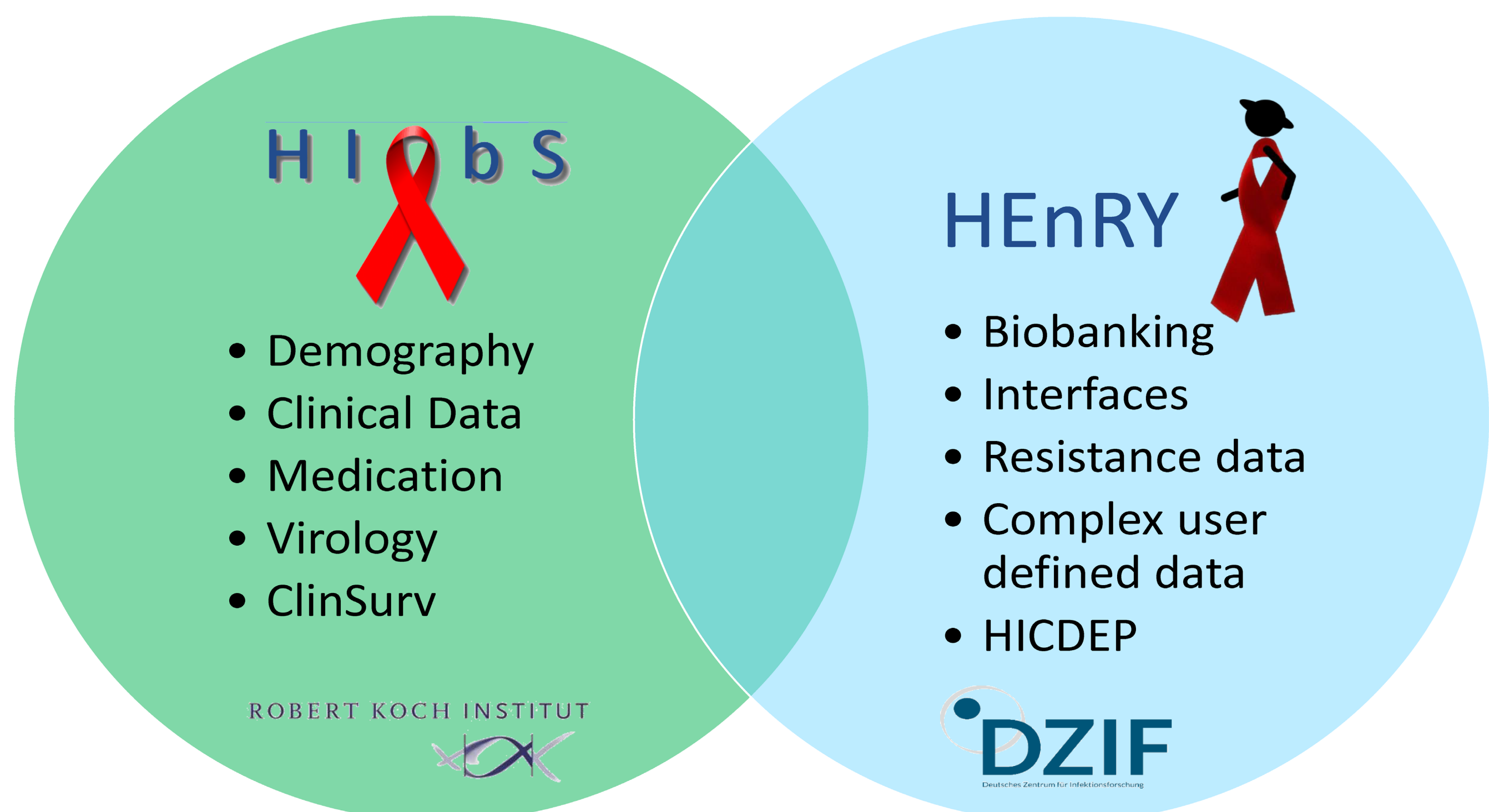
Current Projects

- Multicenter observational trial on serum titers against VZV and MMR and HIV infected patients (C. Schwarze-Zander) - recruitment complete
- Multicenter observational trial on tolerability and efficacy of VZV and MMR vaccination in HIV infected patients with good immune status (C. Schwarze-Zander) - recruitment started
- Multicenter observational trial on late sequelae of Pneumocystis jirovecii pneumonia (G. Behrens) - under development
- Multicenter prospective observational study to characterize immature platelet fraction (IPF) and thrombocyte activation and function alteration in HIV-patients in context of cardiovascular disease (C. Spinner) - applied for funding