

Clinical Data Management for Biomarker Research

Bernd Tschapeller¹, Christian Krainer¹, Thomas Pieber^{1,2,3}

¹JOANNEUM RESEARCH Forschungsgesellschaft mbH – HEALTH Institute for Biomedicine and Health Sciences, Graz, Austria

²CBmed GmbH – Center for Biomarker Research in Medicine, Graz, Austria

³Medical University of Graz, Division of Endocrinology and Diabetology, Graz, Austria

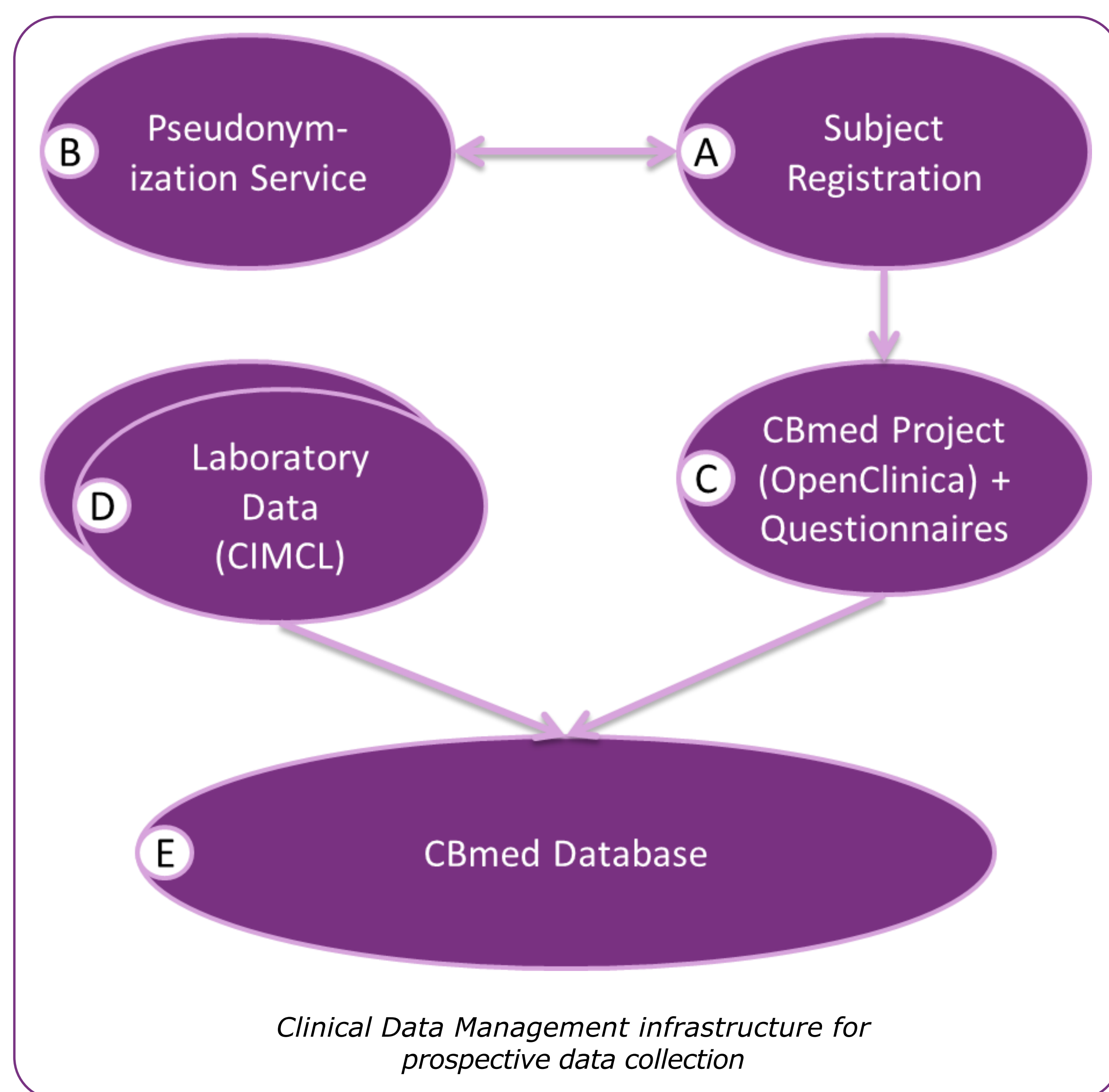
Introduction

- Prospective collection of biospecimens and associated data are key aspects in cohort assembly and clinical trials for biomarker research.
- Only comprehensive data management and anticipatory planning of all data paths ensure high data quality and robust results.

Aim

- Establish a Customized Clinical Data Management platform for prospective biospecimen collections and clinical trials at CBmed to ensure high quality data in compliance with international guidelines and regulatory standards.

Methods



- A** A Subject Registration supports decentralized subject enrolment and facilitates registration with automated processes.
- B** A Pseudonymization Service protects the subjects' identities at all times.
- C** Trial specific data is collected in OpenClinica®. If needed, Questionnaires are collected.
- D** Laboratory and other external data are linked to clinical data.
- E** All collected data will be transferred to the CBmed Database.

Results

- The Pseudonymization Service and the Subject Registration have been developed and are productively used.

Central Subject Registration - CBmedreg

- Clinical data management services including eCRF-development were provided for five prospective trials with a total of more than 100,000 collected items.

Study ID	# of registered subjects	# of eCRFs in status data entry started or data entry completed	# of items with entered data
CBMED_1.6_1	245	245	9737
CBMED_3-1	51	23	135
CBMED32_01	777	792	75801
CBMED_3-4	24	465	2596
CBMED_3-5	108	1357	15126

- A web-based Questionnaire Tool was developed which includes 11 different questionnaires. More than 500 questionnaires were filled-in between July 2015 – February 2018.

Study ID	# of collected questionnaires
CBMED_1.6_1	223
CBMED_3-1	79
CBMED_3-4	104
CBMED_3-5	103

Conclusions

- The provided clinical data management infrastructure allows to collect data in a very structured way.
- Future developments will focus on connection to the CBmed Database and further integration of the Pseudonymization Service in the CBmed workflows.

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