Gefördert durch:

Bundesministerium für Gesundheit

aufgrund eines Beschlusses des Deutschen Bundestages

Förderkennzeichen:
ZMI5-2522DAT14A-O

Cancer Research Data Centre - Design, challenges, and analysis potential of linkage of care-related data.

Kees Kleiheus-van Tol
(ADT e. V.)

...for the project consortium as a whole

ENCR-IACR 2023 Scientific Conference: Pre-Conference Workshop

European Commission

Agenda

- Project motivation
- Project goals
- Use Case
- Schedule and project structure
- Project participants and cooperation partners
- Methodical implementation
- Involvement of technical expertise
- Added value for science and research

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Project motivation

- randomized controlled trials (RCT) = gold standard in medical research, but not suitable for all questions

  → *clinical practice guidelines are limited in their ability to make evidence-based recommendations on specific issues.*

- recognizing and exploiting the potential of the synergy of data collections from clinical cancer registries (CCRs), certified centers of the German Cancer Society, centers of excellence in oncology, and statutory health insurers

Project Objectives

overarching aim:

Develop an IT infrastructure to Compile data collections from disparate data sources.

Subaim:

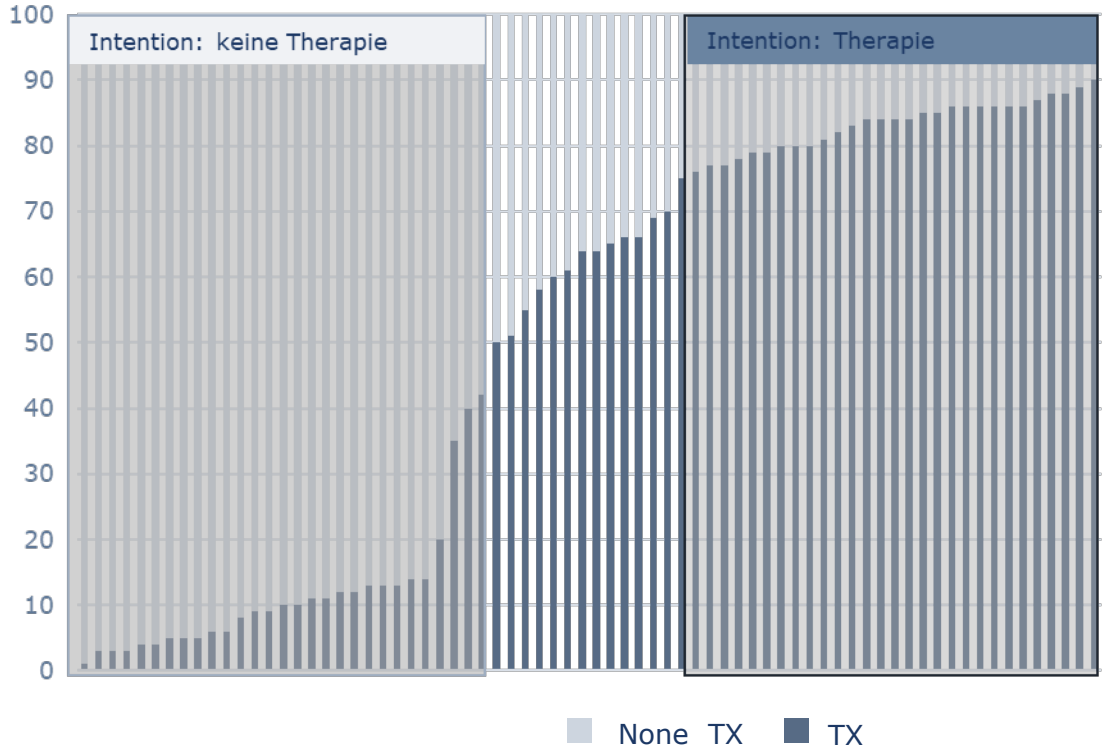
Generation of high-quality evidence for therapy-relevant questions.

→ Testing on the basis of the use case Therapy of colorectal cancer

Addressing highly relevant questions for which there are no evidence-based recommendations in S3 guidelines, reconstructing confounding by indication, and synthesizing primary confounding by indication using AI.

Introduction of the Treatment preference principle into registry research.

- Treatment preference is reconstructed from documented treatment decisions



Scheduled Work Steps - AI:

- Data preparation and feature engineering (identification of influencing factors)
- Simulation confounding by indication with ML methods → Derivation of propensity weights (weighting of influencing factors)
  - 1st approach: Random Forest
  - Parameter tuning with cross validation
- Data evaluation with ML and conventional statistical methods
- Comparison of results

Data analysis for use case colon carcinoma

- Trial emulation under consideration of propensity weights
- Analysis of the following (and further) sample problems

a) ***Adjuvant chemotherapy*** *for colon carcinoma in patients over the age of* ***75 years***

b) ***Adjuvant chemotherapy*** *for colon carcinoma in postoperative* ***stage UICC II***

c) ***Adjuvant chemotherapy*** *for rectum carcinoma following neoadjuvant treatment and surgery*

d) *Choice of* ***systemic therapy depending on molecular subgroups and tumor location***

e) *Choice of laparoscopic and* ***robotic*** *surgery for colon and rectum cancer*

f) ***(reconstruction of) late lines of therapy*** *for patients with metastatic colorectal cancer*

Schedule

Arbeitspakete	Jahr 1												Jahr 2												Jahr 3											
	Sep 22	Okt 22	Nov 22	Dez 22	Jan 23	Feb 23	Mrz 23	Apr 23	Mai 23	Jun 23	Jul 23	Aug 23	Sep 23	Okt 23	Nov 23	Dez 23	Jan 24	Feb 24	Mrz 24	Apr 24	Mai 24	Jun 24	Jul 24	Aug 24	Sep 24	Okt 24	Nov 24	Dez 24	Jan 25	Feb 25	Mrz 25	Apr 25	Mai 25	Jun 25	Jul 25	Aug 25
Organisation																																				
1 Gesamtkonzeption und Koordination																																				
2 Vertragsgestaltung (Weiterleitung, Kooperation)						M																														
3 Datensatzdefinition (Linkage und Auswertung)								M																												
4 Konsultation klinischer Expertise																																				
5 Konzeption und Konsentierung Use&Access																															M					
Dateninfrastruktur																																				
6 Konzeptionsphase (Linkage, Transfer, Harmonisierung)									M																											
7 Abgestimmtes Datenschutzkonzept												M																								
8 Entwicklung und Betrieb Pseudonymisierung+Transfer																																				
9 Workshop zur Vorstellung der etablierten Datenstruktur																																				
10 Lokale Implementierung Pseudonymisierung+Datentransfer																																				
11 Datenbereitstellung Testdatensätze																																				
12 Datenbereitstellung KKR, AOK PLUS, DKTK, DKG																					M															
13 Datenharmonisierung durch ADT																														M						
14 Datenbereitstellung ADT an Auswertestellen																M																				
KI																																				
15 Datenaufbereitung und Feature Engineering (Testdaten)																			M																	
16 Datenaufbereitung und Feature Engineering (Realdaten)																																				
17 Datenauswertung (Training und Performance-Tests)																																				
18 Vergleich mit konventionellen statistischen Methoden																																				
19 Bereitstellung der Propensity-Weights für Analysen																																M				
Datenauswertung Use Cases																																				
20 Studienprotokoll und Ethikvoten																																				
21 Statistischer Analyseplan														M																						
22 Datenauswertung																																	M			
Ergebnisverwertung																																				
23 Transfer in LL-Programm																																				
24 Ergebnisvorstellung und Erstellung Publikation																																				M
25 Nachnutzbares Toolkit der Dateninfrastruktur																																				
Meilensteine						*1*		*3*	*2*			*8*		*5*		*6*			*7*		*4*								*9*		*10*	*11*	*12*		*13*

Projekt structure

Project Management and Network Coordination:

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Project participants and cooperation partners

Project participants

- Association of German DKG-Certified Colorectal Cancer Centers (**addz e.V.**)
- Association of German Tumor Centers (**ADT e.V.**)
- Clinical Communication Platform (**CCP**) in the German Consortium for Translational Cancer Research (**DKTK**)
- German Cancer Research Center (DKFZ)
- German Cancer Society (**DKG**)
- Hessian State Examination and Investigation Office in Health Care, Dept. IV **Hessian Cancer Registry**
- **Clinical Cancer Registry for Brandenburg and Berlin** gGmbH
- Chemnitz Hospital non-profit GmbH - **Clinical Cancer Registry Chemnitz**
- Southwest Saxon Tumor Center Zwickau e.V., **Clinical Cancer Registry Zwickau**
- **Clinical Cancer Registry Dresden**
- **Clinical Cancer Registry Leipzig**
- **OnkoZert** GmbH
- Medical Clinic 2, **Goethe University Hospital Frankfurt/M.**, Department of Medicine
- **University Medical Center Freiburg**, Institute for Medical Bioinformation and Systems Medicine
- University of Regensburg, **Tumor Center Regensburg**, Center for Quality Assurance and Health Services Research
- TU Dresden, Center for Evidence-Based Health Care (**ZEGV**) and Independent Trusteeship (**THS)**

Cooperation partners

- AOK PLUS, The Health Insurance Fund for Saxony and Thuringia
- National Center for Tumor Diseases Dresden
- German ILCO e.V., national association
- Clinicians from Bochum and Bremen

Methodological implementation

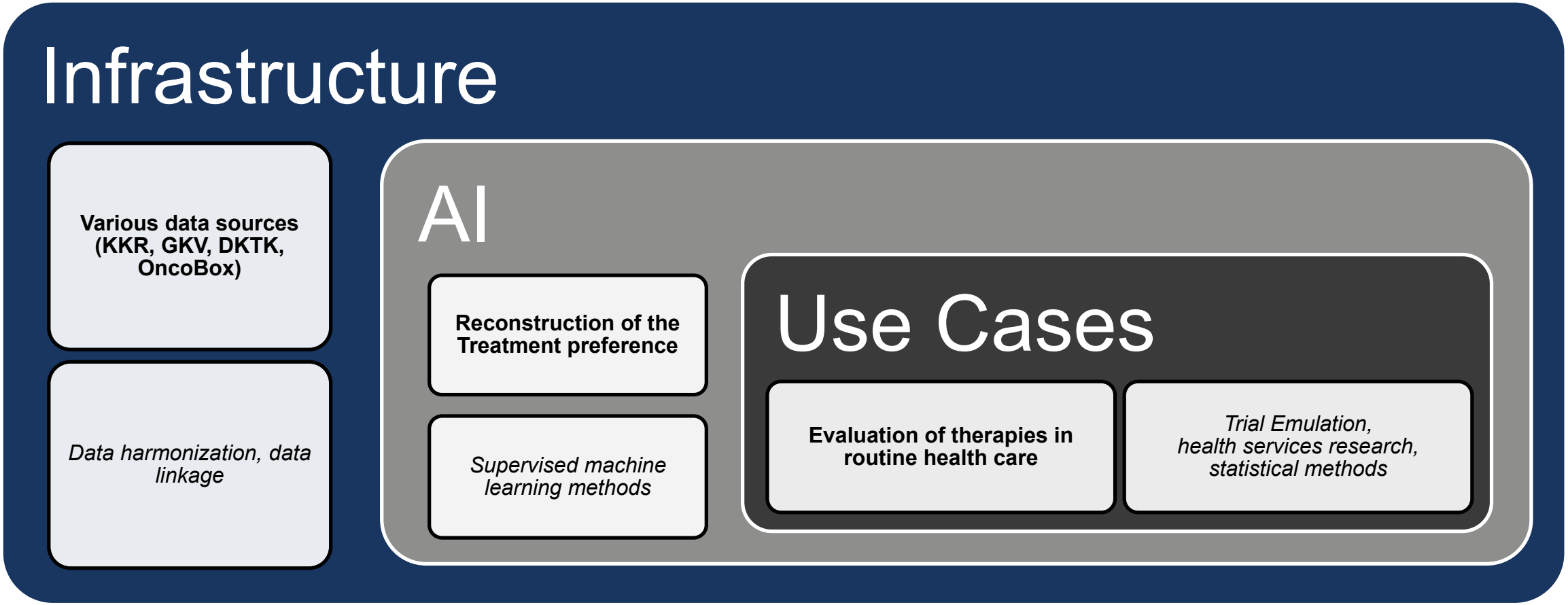

Illustration: Schematic representation of the project components.

Methodological implementation

Basis of data:

Integrated care-related data

Methods:

- Occasional linkage of complementary databases (CCR, SHI, CCC, DKTK, Oncobox Research).
  - Bridgehead model
  - data linkage by SMPC
- Comprehensive data harmonization
- Use of modern machine learning and statistical methods

Data Flow Chart

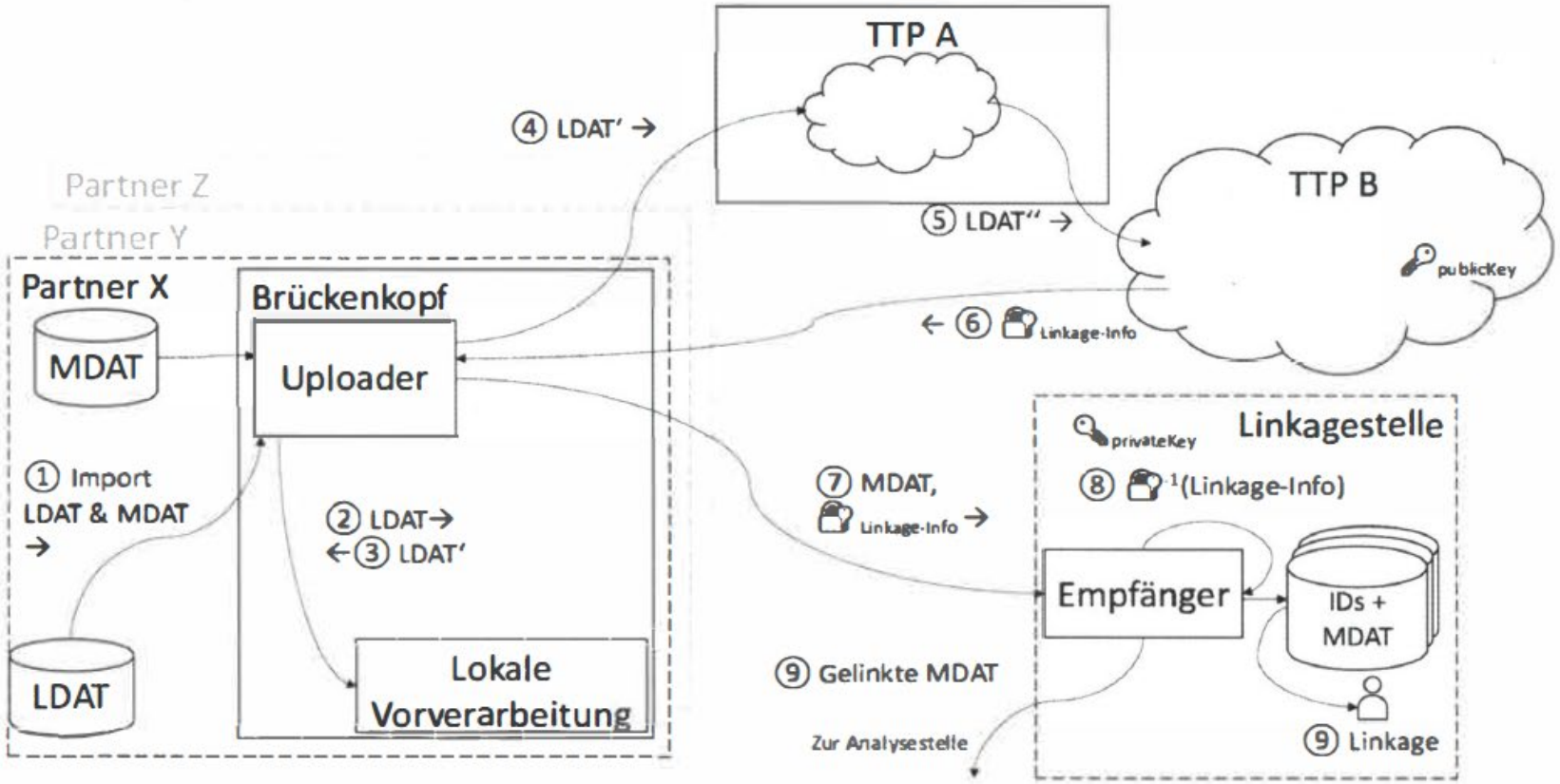

Abbildung 3: Schematische Darstellung des konzipierten Pseudonymisierungsablaufs.

Involvement of Expertise

Interdisciplinarity:

- Consideration/consultation of clinical expertise
- Involvement: physicians, patient representatives, self-help groups, guideline group "Colorectal Carcinoma"
- Legal support: Consideration of country-specific data protection regulations

Added value for science and research

Sustainable Development Approach:

- Implementation as a toolkit
  - → open-source licensed and documented under Creative Commons
- Conception of a Use&Access procedure for scientific use
  - → integration into the "ecosystem" of the different research data centers in Germany
  - → open integration into the scientific community

onko Forschungs Daten Zentrum

Thank you

to all project participants and those interested!

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