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Automated clinical routine data integration for Data Safety Monitoring Board (DSMB) reports in a personalized phase I study

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Background

The ongoing phase I BaseTIL trial (NCT04165967) evaluates feasibility and safety of Adoptive Cell Therapy (ACT) with tumor-infiltrating lymphocytes (TILs) in nine patients with advanced melanoma. TIL therapy is a personalized cell-based immunotherapy. The major study interventions are depicted in Fig 1.

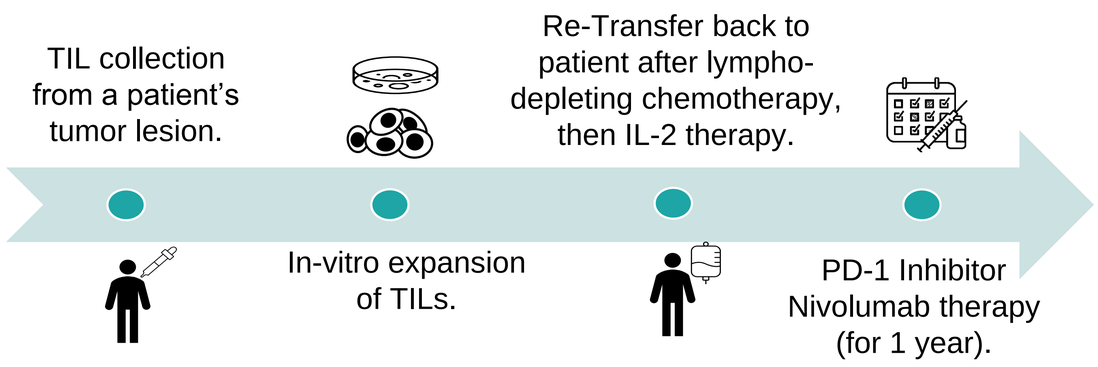

Figure 1: Simplified depiction of tumor-infiltrating lymphocyte (TIL) therapy used in this study.

To safeguard the interests of the patients, the independent DSMB met after the first and third patient and requested *continuous* charts of vital signs and laboratory values (e.g., heart rate, blood pressure, blood count).

Issue:
Trial data is not continuously available in the electronic case report form (eCRF) according to study protocol. Therefore, we extracted the continuously recorded data from routine care, available in the Clinical Data Warehouse (CDWH) of the University Hospital Basel (USB) (Fig. 2).

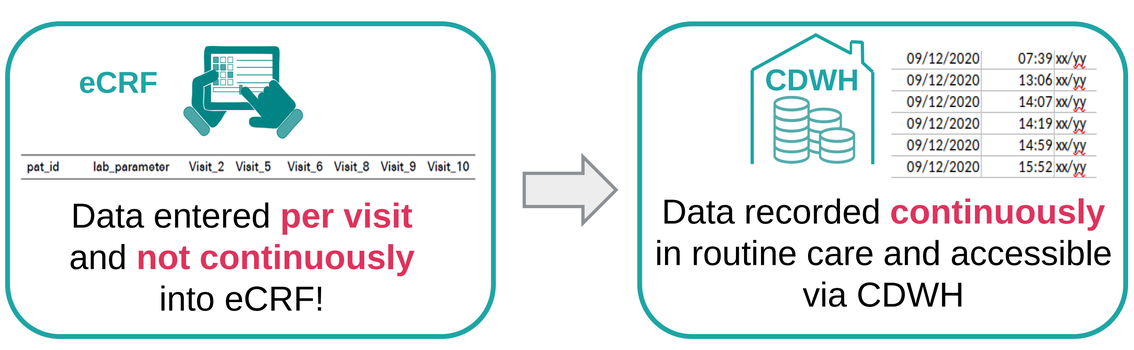

Figure 2: Reason, why routine data from the CDWH were needed to fulfill the requests of the DSMB board.

Methods

We used a "power-user" access to the CDWH of the USB to extract the requested continuous routine data and automatically integrated the data with the eCRF data. The steps performed from data identification to export and merging with the study data from the eCRF to the final visualization for the DSMB report are shown in Fig.3.

Figure 3: The steps needed from data and patient identification to export, cleaning and merging the routine data with the study data from the eCRF to the final visualization for the DSMB report.

Challenges

- Identification and extraction of the correct data from different views stored in the CDWH (1-2 months).
  - ☞ Different identification and laboratory codes for the same observable due to different systems.
- Pseudonymization of patient IDs (hospital vs. study ID).
- Different granularity and structure between different systems (e.g., data from ICU stays vs. stationary visits).

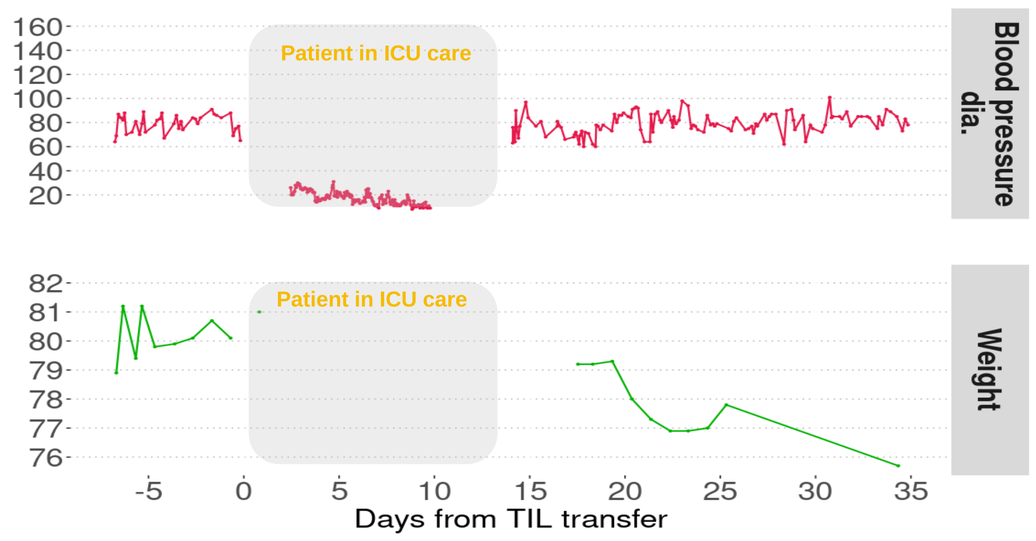

Figure 4: An example for one challenge we faced when merging routine data from different sources, like the ICU and stationary care.

Conclusions

- CDWH at the USB allows easy reuse of routine data without manual data entry into an eCRF.
- Different identifiers for patients & laboratories remain a challenge, especially when comparing different wards
- After an automated routine is set up, data quality & timeliness of data entry can be improved significantly
- A close collaboration between study team, the CDWH team, project managers, & the data scientists is essential to the success of the study.