Data processing and data quality in a dynamic prospective cohort study in the preschool setting – first experiences from the ‘GIF M-V’ project with the eCRF solution re:forms

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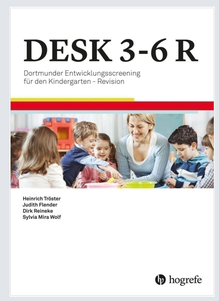
Introduction

Since 2010 / 2011:

- Federal state law for child day care and preschools (KiföG M-V): early detection of developmental risks (dr) via “Dortmund Developmental Screening for Preschools (DESK 3-6 R)”
- Project “GIF M-V”: evaluation of the effectiveness of the targeted promotion for children with dr based on DESK data



Until 2023:

- raw data entry via Cardiff TeleForm®: automatic scanning of forms; verification by student employees; completeness check/plausibility check carried out by manual data export to SAS ➔ Problem: unrecognised scanning errors ➔ reduced raw data quality (e.g. not all pages of a questionnaire scanned; scan program froze leading to uncertainty as to whether the scan had been saved ➔ occasional duplicate data records ➔ manual effort when generating an evaluation data set using SAS

Since 2024:

- Using re:forms (www.re-forms.de) for web-based data capture (eCRF) based on a project-specific criteria catalogue

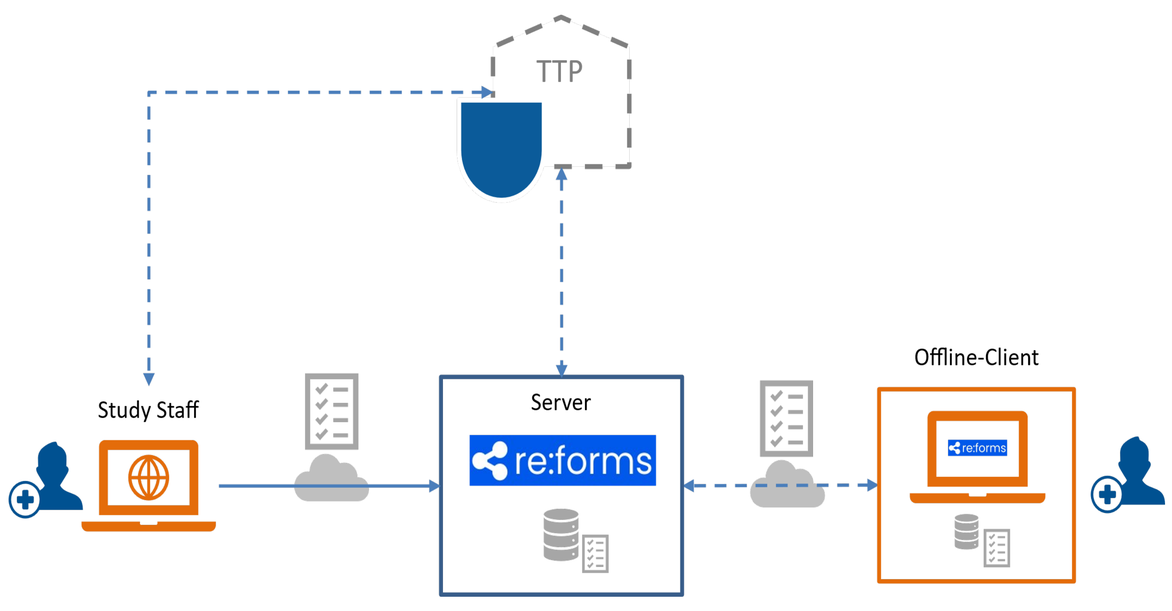
Methods

Project specific catalogue of requirements for a web-based data capture solution includes:

1. intuitive creation of eCRFs by project staff without IT knowledge
2. roles/authorisation assignment per employee with the option to restrict data/forms
3. web-based, location-independent data entry incl. automated completeness check/plausibility check
4. configurable rules, warnings and input instructions

5. versioning of data entries
6. option to integrate services of the Trusted Third Party (separate storage of person identifying data with E-PIX®, automated pseudonymization with gPAS®)
7. automatic export of pseudonymised data to target database for data analysis via SAS and SPSS

- re:forms can be used in online mode (centralised provision of eCRFs) and as an offline client.
- All eCRF can be individually defined via a user interface.



- Necessary data capture forms configured by the GIF-MV project staff
- All data capture processes converted to direct web-based data entry
- Corresponding quality-related notes (rules, notes, checks) configured
- re:forms went live in October 2024
- A total of 7,912 data records have already been collected successfully (as of 29/08/2025).

Results

- The combination of eCRF and direct user feedback provides indications of higher data quality at the raw data level, e.g. the scanning problems mentioned above no longer exist. Therefore, in terms of time, re:forms leads to a shortening of the data processing.
- The re:forms functionality for data versioning now allows student employees to complete missing data (e.g. missing date of birth). Before, this was the task of the medical documentarian, who created various SAS scripts for this purpose. Thus, re:forms also offers the potential for cost savings.

Discussion

- re:forms does not only save paper, but offers the opportunity of even higher data quality already at the time of data entry.
- In the future, trained preschool teachers will be enabled to document primary data directly and independently using re:forms.

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