

Evaluation of an offline-capable eCRF solution for dementia research as part of the DECIDE-2 project

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Introduction

The DECIDE-2 project [1] aims to increase the autonomy of people with dementia and reduce the burden of relatives and caregivers. This shall be achieved by integrating Advance Care Decision Making (ACD) into the evidence-based concept of Dementia Care Management (DeCM). The ACD-DeCM approach will be adapted for dementia care practice in a participatory process. Its effectiveness will be evaluated in a randomised controlled single-blind study.

DECIDE-2 has project-specific requirements regarding data collection, aiming to make it as efficient as possible while obtaining high-quality data. Its requirements for an eCRF software solution (electronic Case Report Form) include:

- Study staff creates and maintains forms (eCRF)
- Scientists can export data (e.g. in .csv) independently
- Offline (server unavailable) and online use (browser on server) are possible (reliable internet connections are not always available on site)
- Predefined rules trigger demands (support and care measures for person with dementia or their relatives), processed by the study staff.

The software re:forms [2] can implement the individual research project's requirements. It will be evaluated for collecting person identifying data and medical data based on project requirements. This aims to check the re:forms suitability and to test the software in practical use.

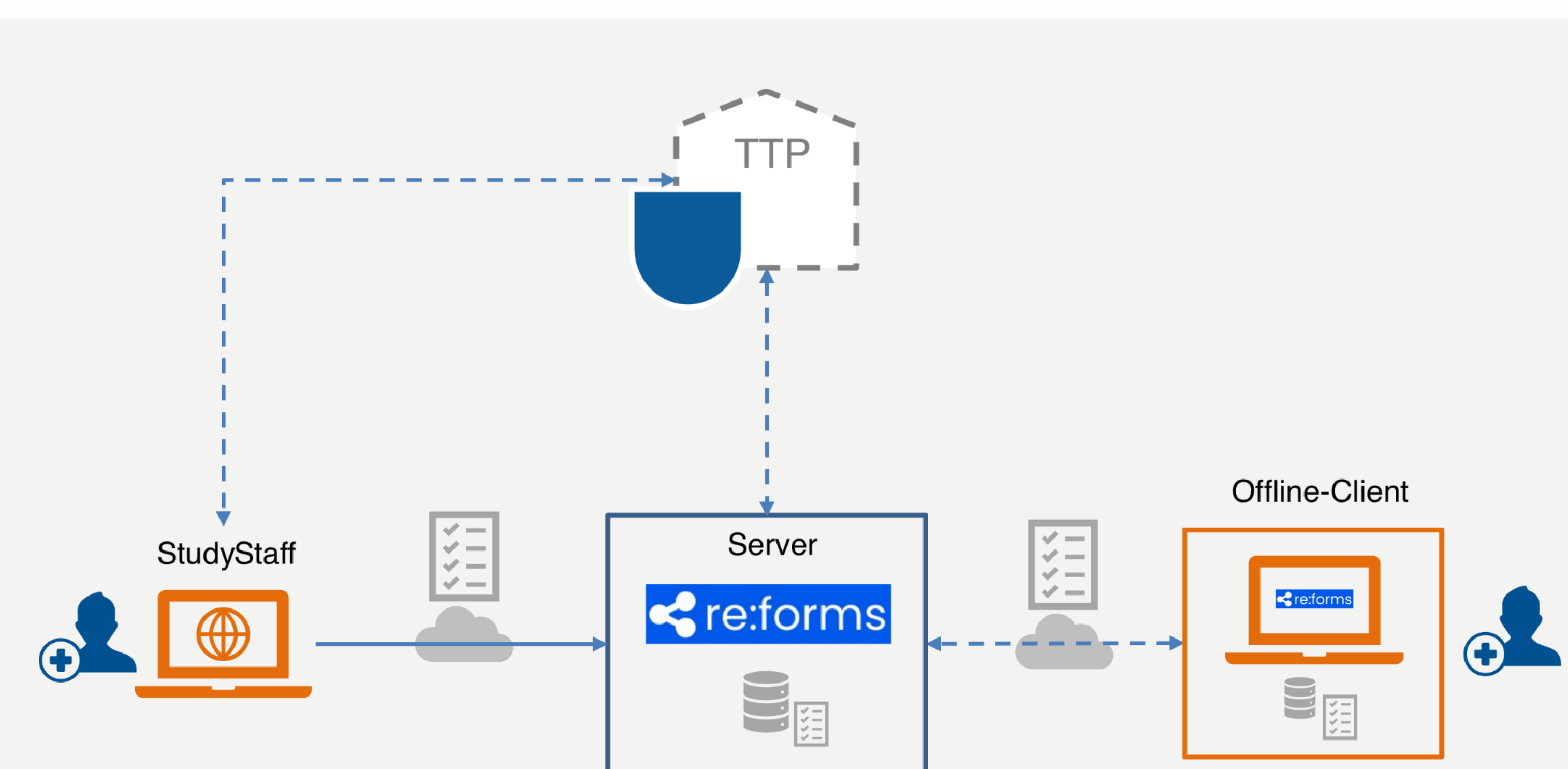
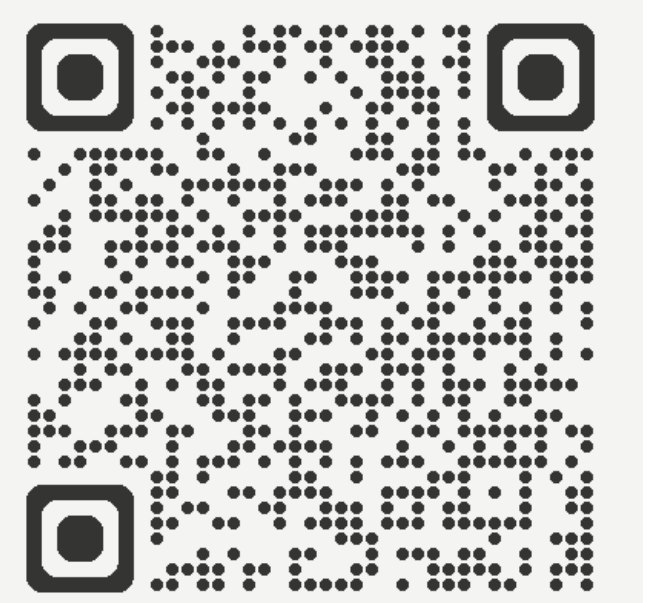


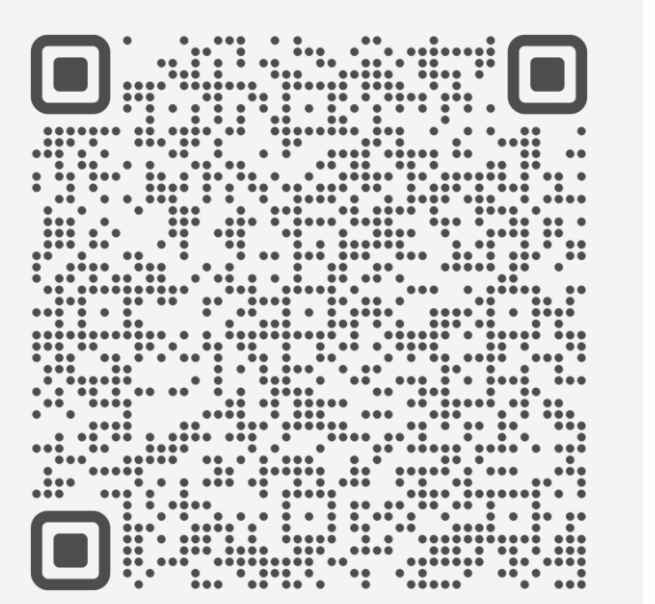
Figure 1: Overview of re:forms use cases and workflows

Methods

A test infrastructure was set up for trial operation of re:forms. The project staff was trained to use re:forms via video conference for approximately 60 minutes, covering 'data collection' and 'eCRF design'. Project-specific requirements and suggestions for UI and technical optimisations were identified by study staff and scientists (e.g. patient-specific custom notes). The Software developers implemented these improvements into the current version of re:forms. During the test phase, the form-design, data collection and offline/online data synchronisation processes were tested. However, no productive data was gathered.



re-forms.de



Project DECIDE-2

Results

The DECIDE-2 project's evaluation helped increasing re:forms software quality and improve its usability during the pilot phase. DECIDE-2 benefits equally from those improvements. The 46 forms designed in the test phase will likely be used in production, too. Users preferred applying re:forms online, with only few meaningful cases of parallel offline use. The project requirements were realised through the use of re:forms.



Figure 2: Current features of re:forms

Conclusion

Generally, re:forms meets the requirements and represents a potentially suitable software solution for DECIDE-2. It focusses on form-design and maintenance by project staff, the combination of online/offline data collection, and corresponding synchronisation processes. However, a final statement on the successful introduction of re:forms is anticipated. The practical phase, which started in April 2025 and is currently ongoing, will show whether re:forms can meet the challenges of daily data collection. Although its application in routine practice is still pending, the evaluation already indicates that re:forms is suitable for use in other projects. The software is continuously being improved by the Institute for Community Medicine.

Sources:

- [1] Bundesministerium für Bildung und Forschung. DECIDE 2: Entscheidungsassistenz bei gesundheitlicher Vorausplanung für Menschen mit Demenz [Internet]. Berlin: Bundesministerium für Bildung und Forschung [cited 2025 Apr 8]. Available from: <https://www.gesundheitsforschung-bmbf.de/de/decide-2-entscheidungsassistenz-bei-gesundheitlicher-vorausplanung-fur-menschen-mit-demenz-17996.php>
- [2] Institut für Community Medicine. re:forms - Formulare (eCRFs) neu gedacht [Internet]. Greifswald: Peter Penndorf; 2025 [cited 2025 Apr 8]. Available from: <https://re-forms.de>