

TRANSFoRm: connectivity infrastructure to embed eCRFs into EHRs

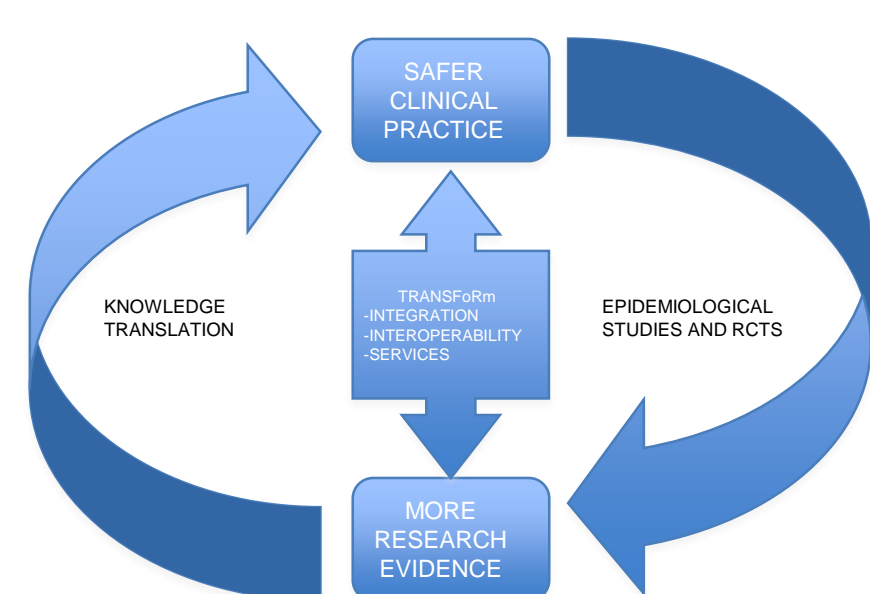


The TRANSFoRm Consortium, www.transformproject.eu

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Introduction



Background

Combining routine healthcare tasks and clinical trial tasks is essential to improve quality, throughput and affordability of clinical trials

There is a need to leverage/augment local infrastructure rather than displace it

Key issues are compatible workflows and semantic interoperability of data

Ontologies are considered a powerful mechanism for achieving data interoperability

A need to focus on generic, standards-based approaches, rather than ad-hoc

A need to extend existing CDISC standards to enable data pre-load from the underlying EHR and improve workflow

Objectives of TRANSFoRm

A comprehensive digital infrastructure supporting the Learning Healthcare System

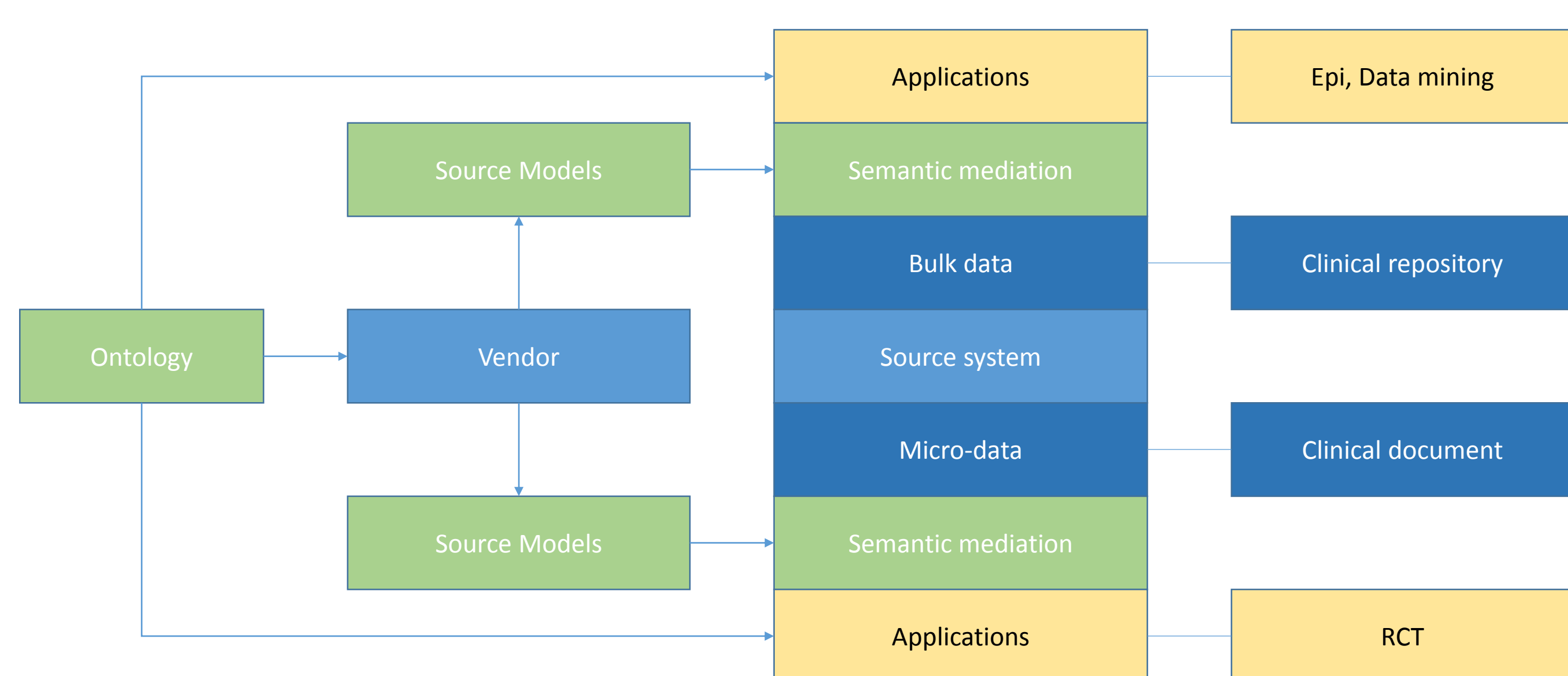
Integration of Clinical research and routine healthcare

Data access and integration through ontology-driven semantic mediation

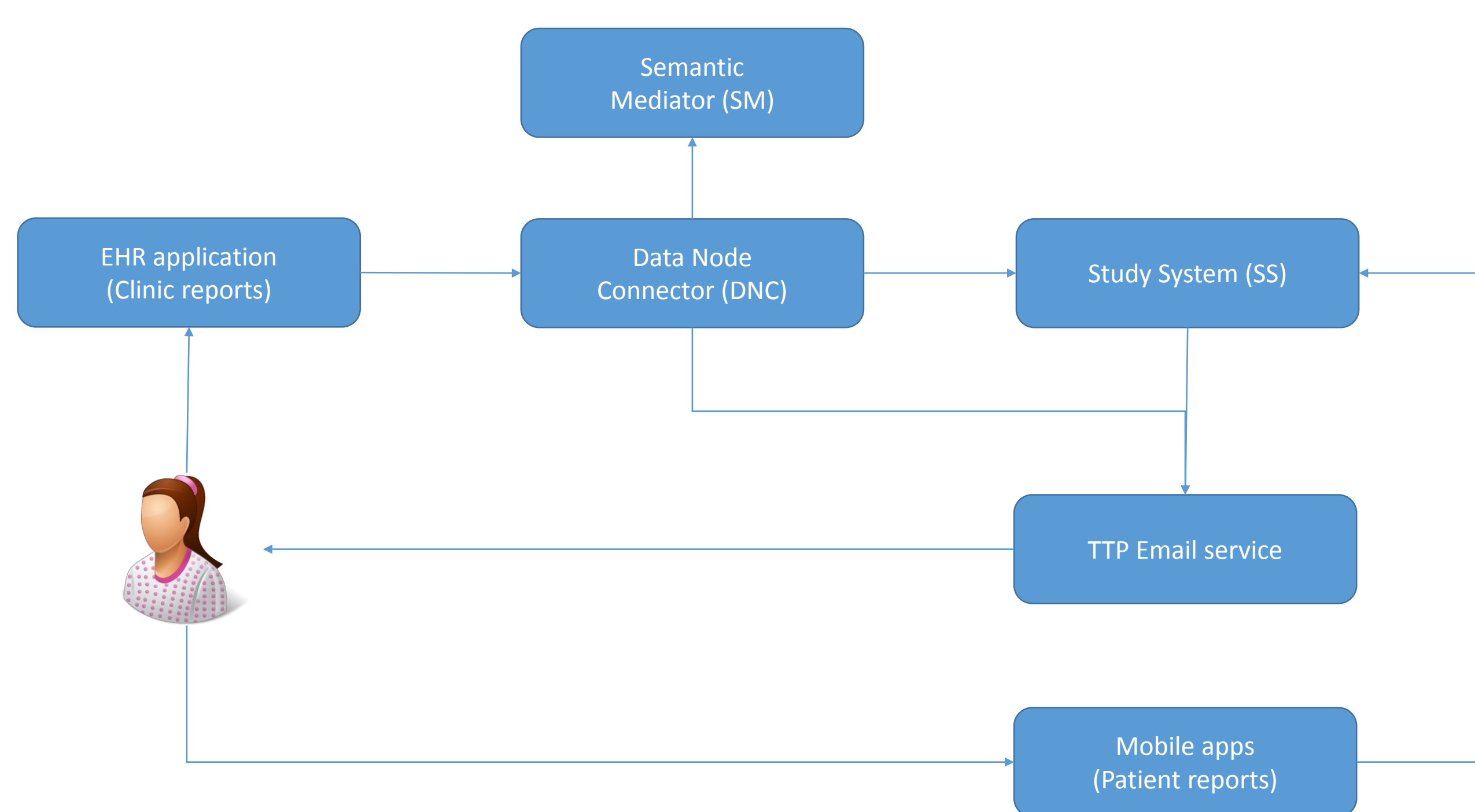
SOA for integration of software components, both local and remote

Evaluation of the approach using commercial partners and practices within a full RCT

Applications and their data



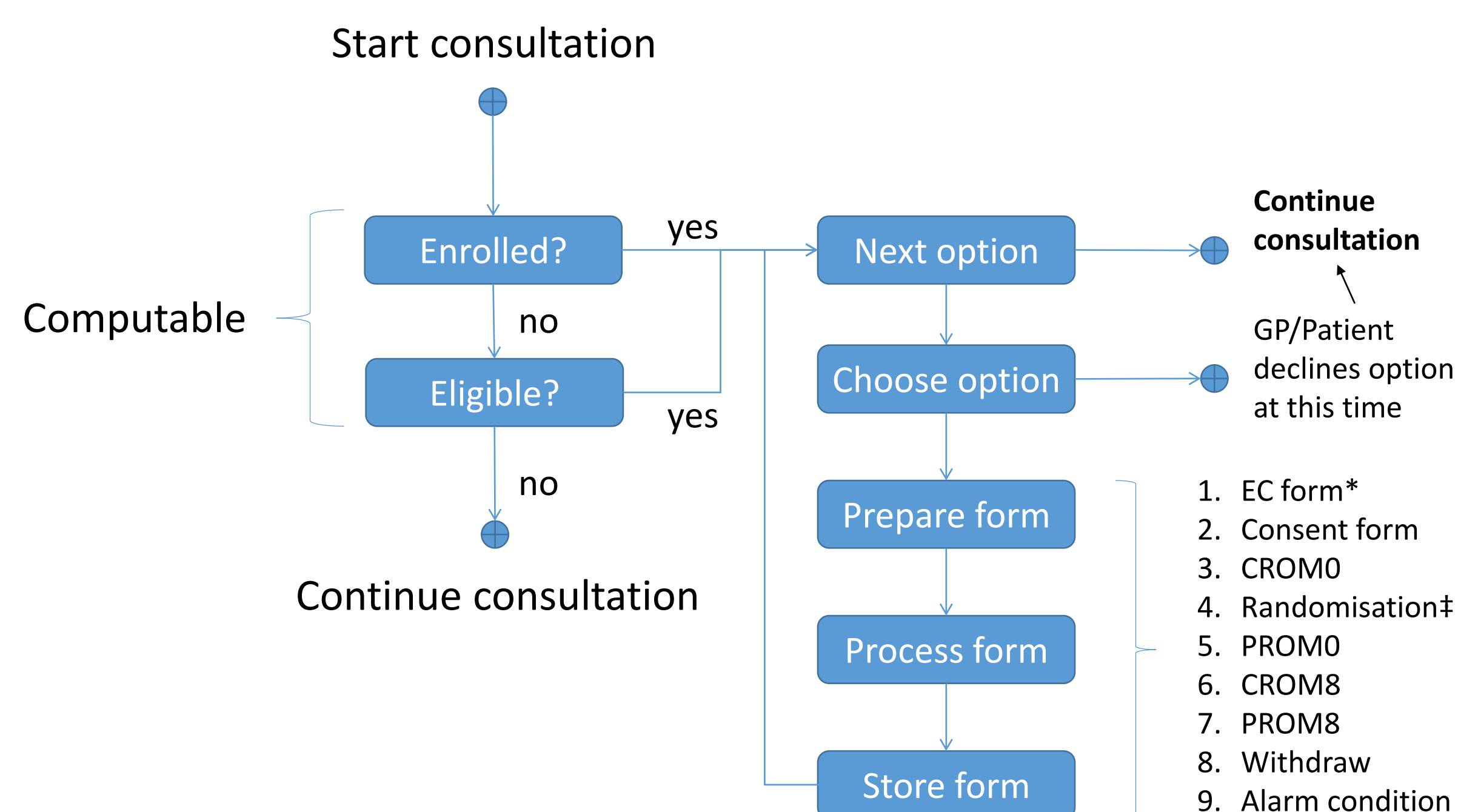
RCT application architecture



All components interact through RESTful web services

Initiates action/call

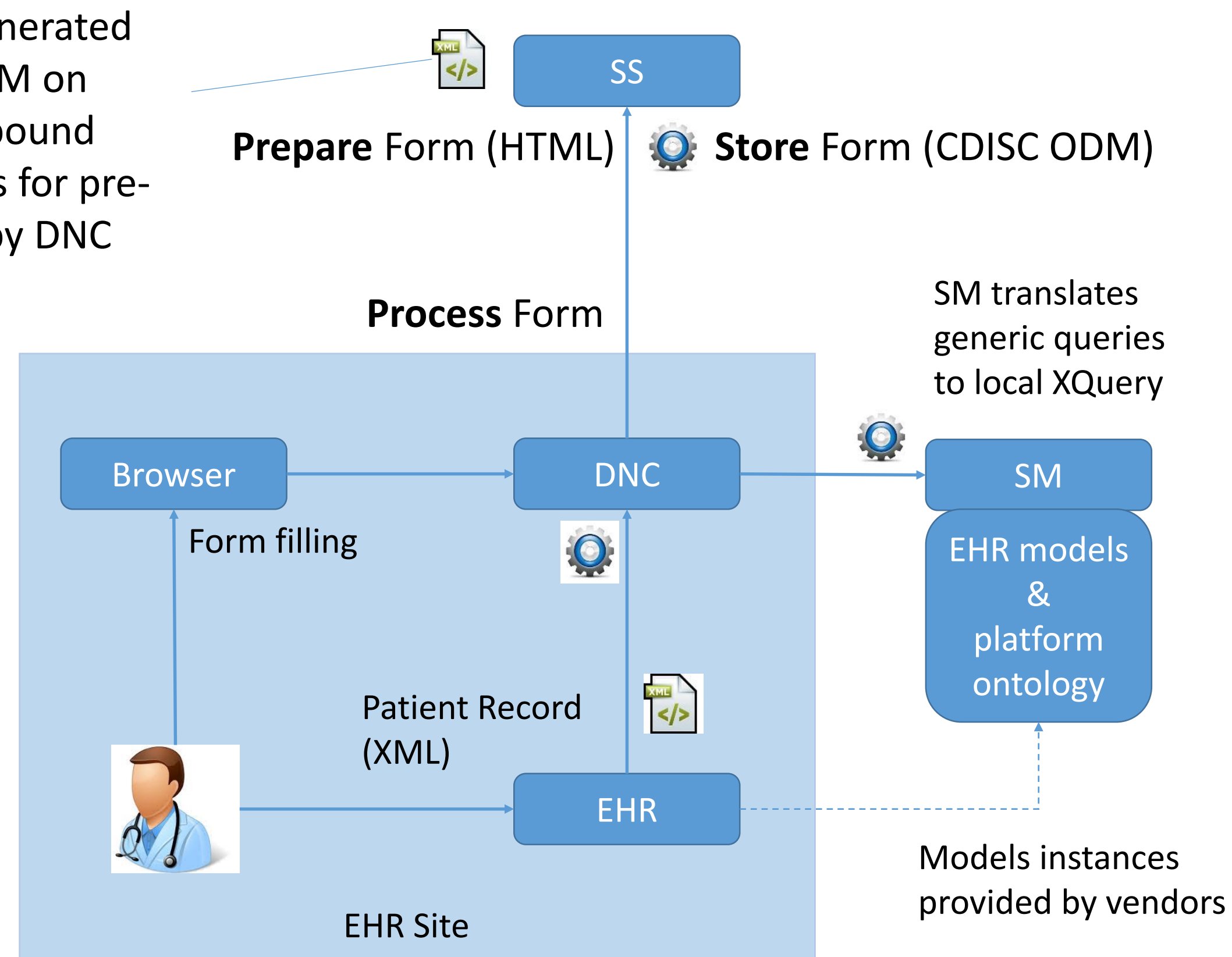
Interaction of study/consultation workflow



CROM – Clinician reported outcome measures; PROM – Patient reported outcome measures
 * EC form allows for collection of non-computable EC and confirmation of overall EC
 ‡ Patients and physicians are not blinded in the GERD study. A form delivers the randomisation and is stored in the EHR.

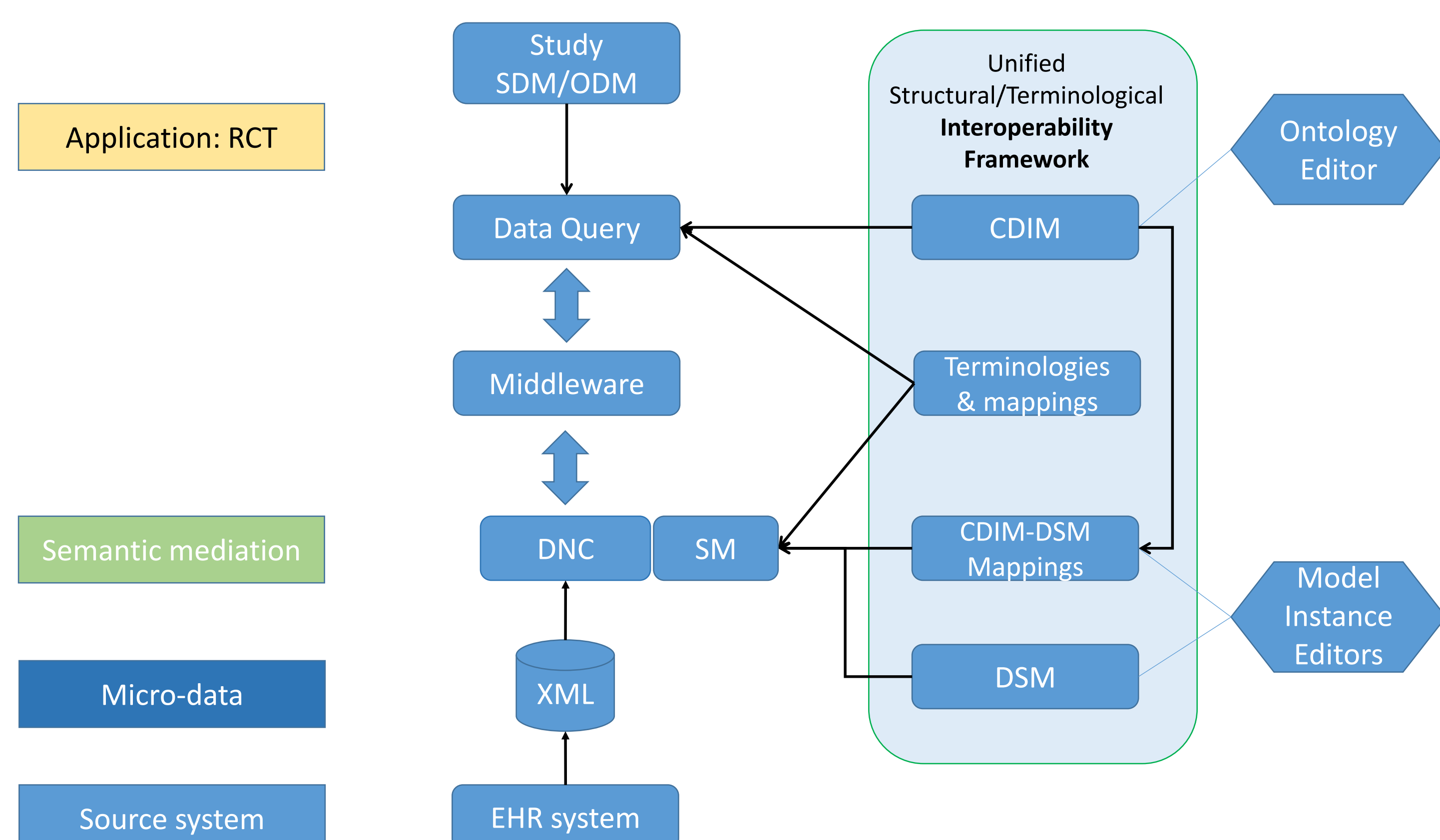
Form processing

Form HTML generated from CDISC:SDM on demand with bound generic queries for pre-loading fields by DNC

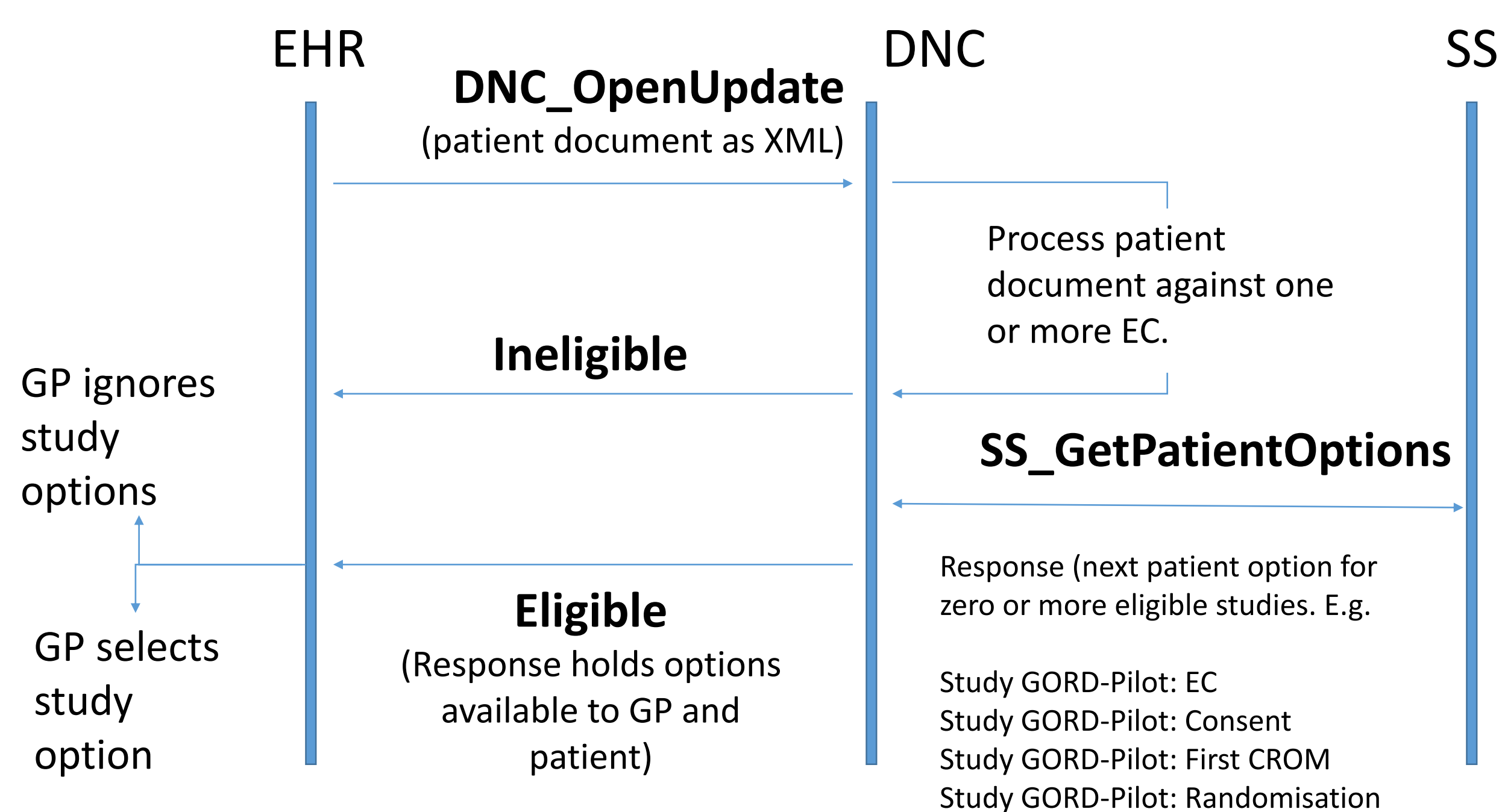


Initiates action/call

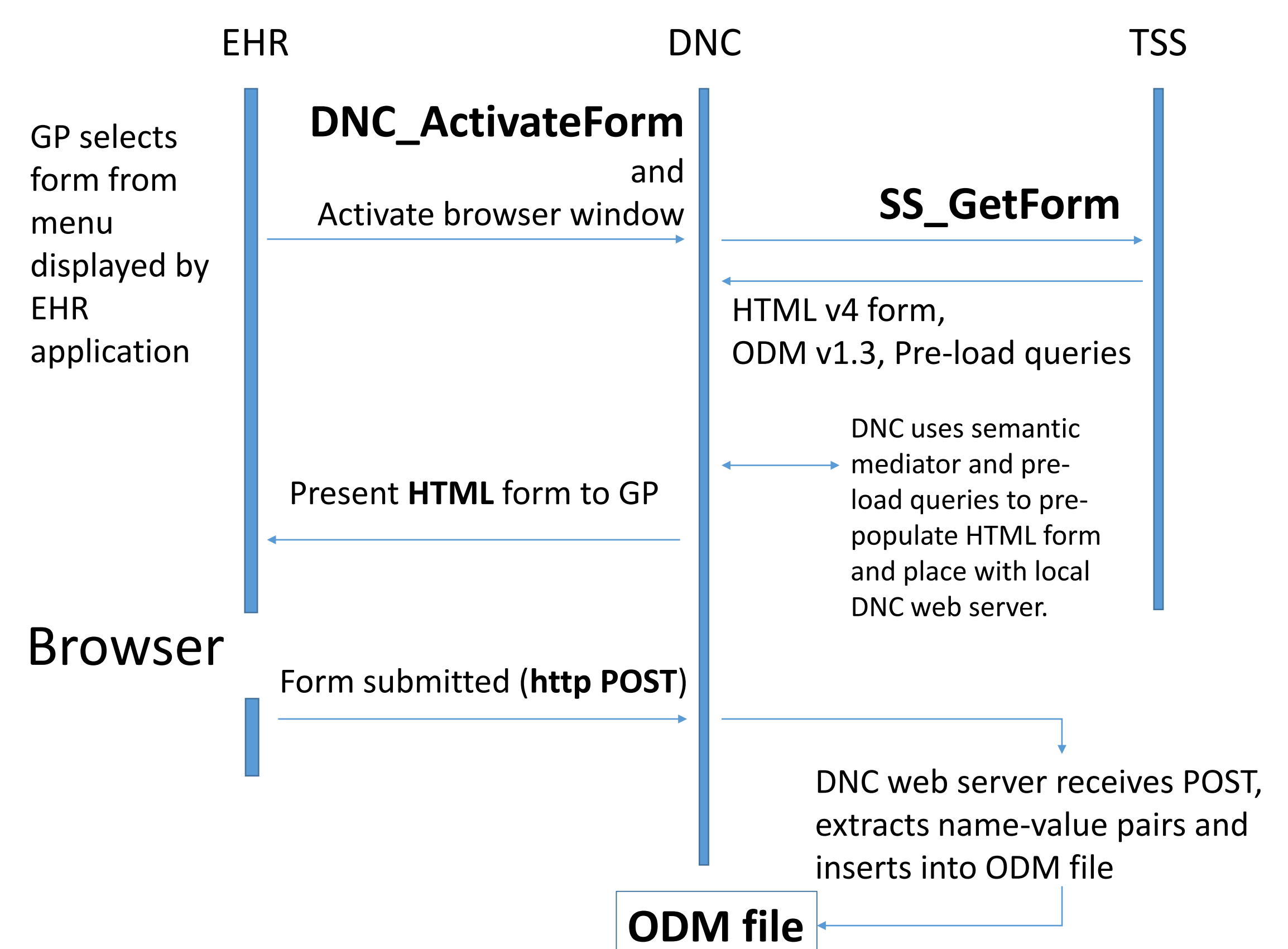
Data interoperability



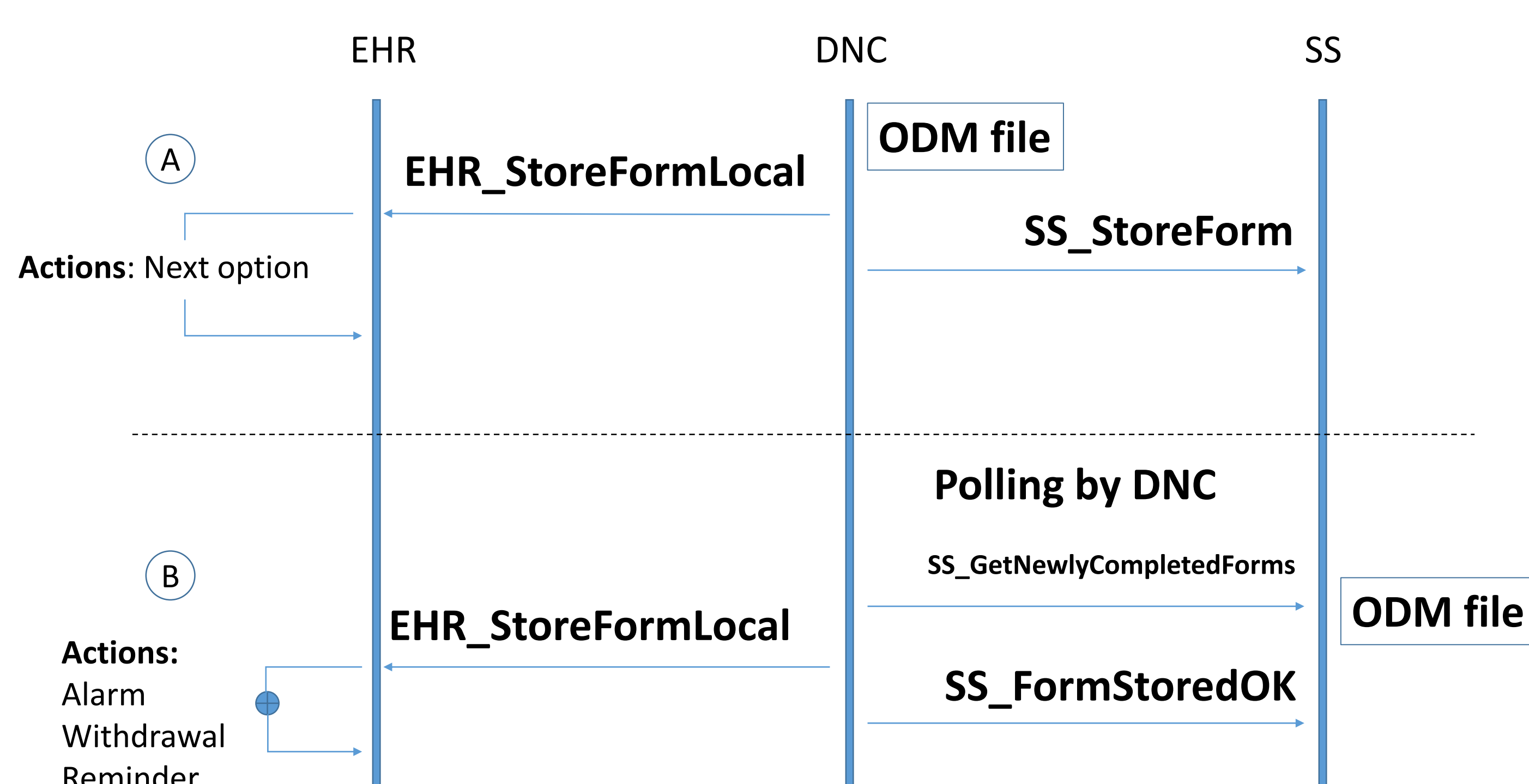
Detecting eligible patients



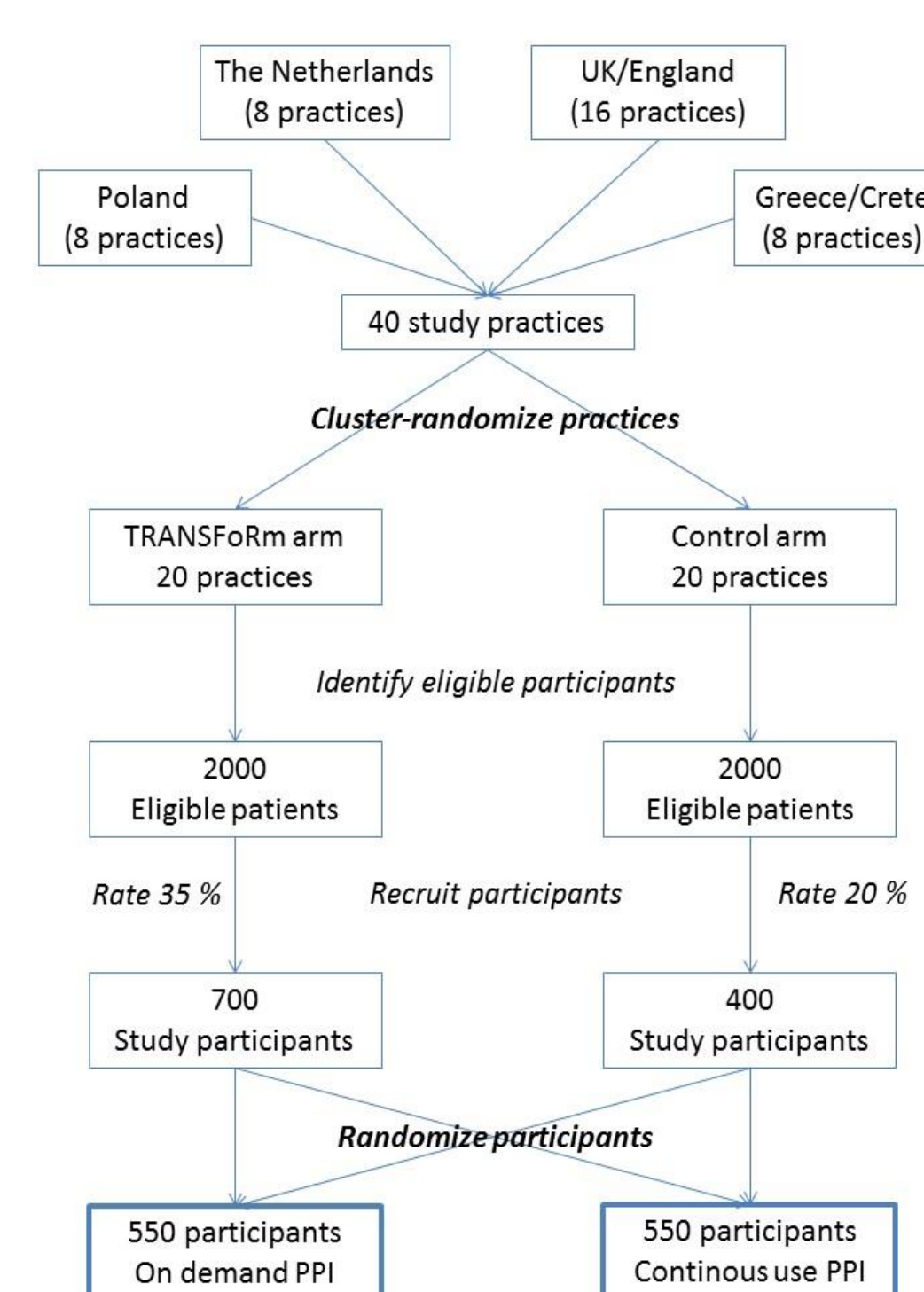
Filling Forms



Storing forms



GERD RCT evaluation plan



Validation: Mixed-methods feasibility study

- GCP certification
- Basic validation will be performed in all localities
- Extended validation will be performed in the Netherlands

Evaluation: Meta-study on RCT (PPI on demand vs continuous)

- Proportion of patients successfully recruited using TRANSFoRm vs. control
- 20 practices per arm (recruitment rate 20-35%, ICC=5, P=.05, Power=99%)
- Permuted, stratified within-locality randomization (1:1 AR)
- For enough power for research question recruit 700 patients (17.5 per centre).
- 4 month recruitment, 8 week follow up

TRANSFoRm vs Control arm

Feature	TRANSFoRm	Control
Recruitment	Query against EHR	Manual
Randomization	Automatic	Manual (same algorithm)
Consent	Confirmation email	Signed paper
CROMs (eCRFs)	Integrated	Web-based
PROMs	Web/Smart Phone	Physical materials
Monitoring	Reporting workbench	Manual

Current status & conclusion

Validation study (Poland only): Ethical approval received
 Evaluation study:

Locality	Vendor contract	GPs recruited	Ethics approval	Evaluation status
PL	Yes	Yes	Yes	ongoing
NL	Imminent	Yes	Yes	Imminent
GR (Crete)	Yes	Yes	Yes	Development
UK-1	Yes	Yes	Yes	Testing
UK-2	Yes	Yes	Yes	Development

Discussion

Platform software components are complete and distributed to vendors along with documentation and a full-platform simulator to aid vendor development. The components are installed in Poland and evaluation is under way. Deployment and evaluation will soon take place in the Netherlands. Development is continuing with other vendors.

Contacts

RCT Technical Infrastructure

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