

Paper AD14

Building a large scale clinical trial IT system with in- house software and OpenClinica®

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Agenda

- Large-scale clinical trials run by OxPop
- Why we used OpenClinica for AscendPlus trial
- Why and how we complemented OpenClinica with in-house software
- The issues we encountered and how we overcame them



Large-scale, streamlined trials run by CTSU

- Clinical Trials Unit within OxPop
- Streamlined trials
- One of trials remotely followed participants from a single coordinating centre - ASCEND

A UK trial designed to estimate the effect of allocation to oral semaglutide vs. placebo in 20,000 people with type 2 diabetes

- Follow up for 5 years on major adverse cardiovascular events using National Health Service data to collect most outcomes of interest
- Highly streamlined (following on from the ASCEND trial)
- Recruitment based on postal invitations in partnership with NHS
- Communication with participants via web, phone or letters
- Call centre and a team of research nurses handles communication
- No face-to-face visits
- Study treatment posted to participants

A cloud-based, open-source clinical data management and electronic data capture system

- Direct involvement of participants via Participate module
- Rapid eCRF design
- Reporting module Insight
- Extensible via APIs
- Auditing, support for regulatory submissions, issue tracking

Areas in which we complemented OpenClinica with our software

- Recruitment
- Managing sites and participants' appointments
- Randomisation
- Managing participant statuses and progression through study
- Handling Adverse Events
- Managing treatment supply
- Email and SMS communication with participants

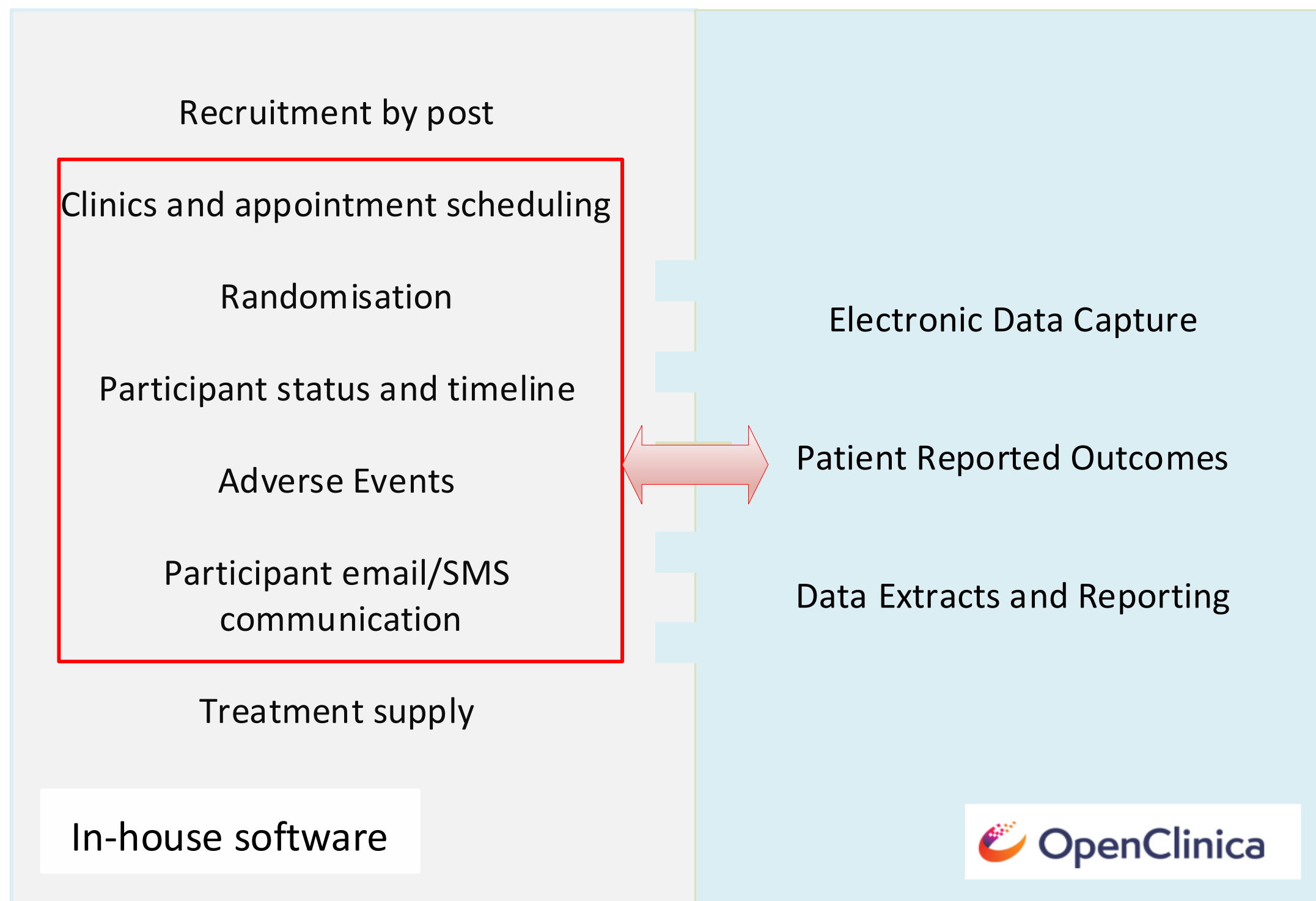
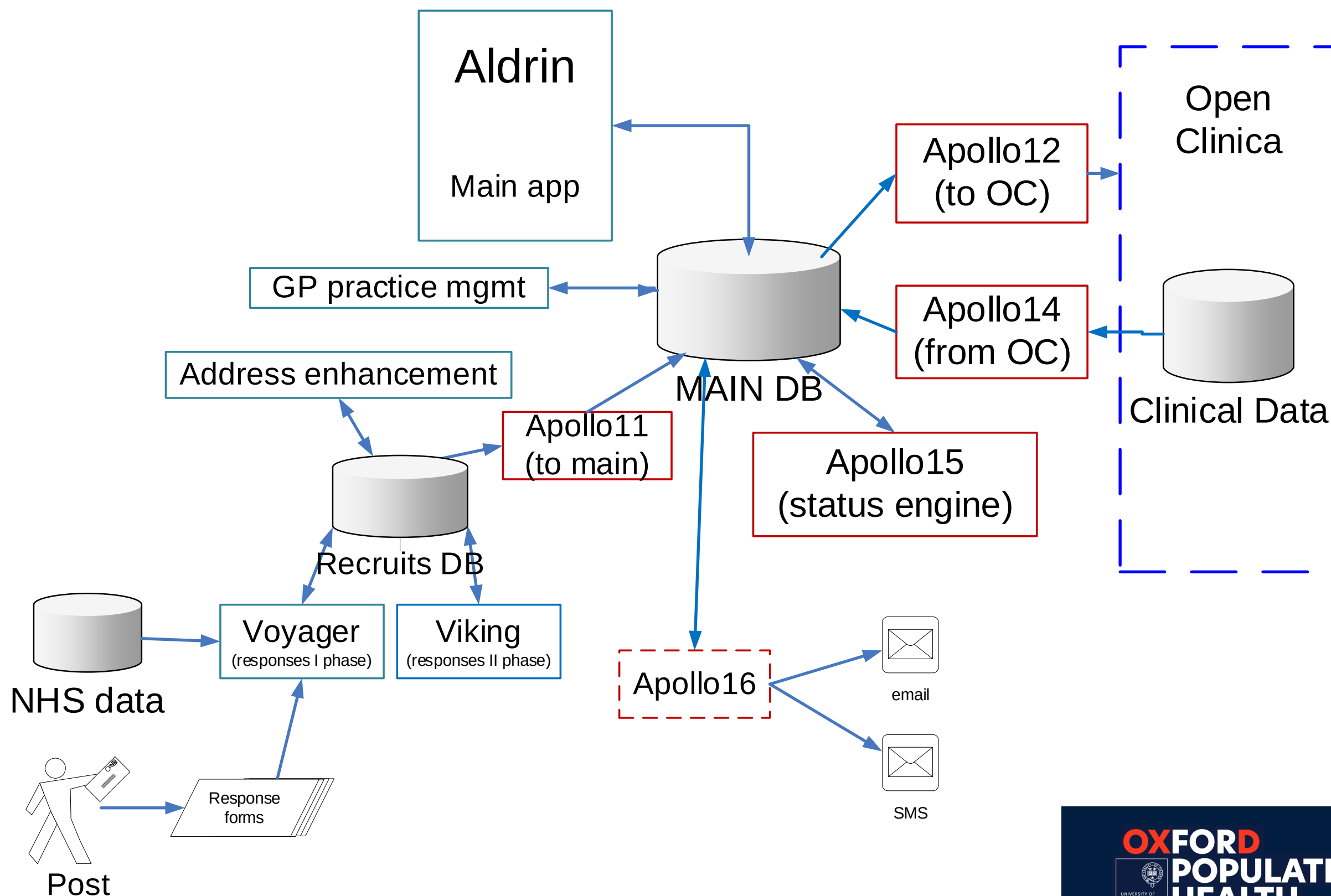


Diagram of the system



Options for data exchange

One-way exchange principle

OpenClinica to the in-house software:

- Generating data extract using OC interface
 - Access to the extract via link
 - Once-per day frequency
- Pulling individual participant data from OC using APIs

The in-house software to OpenClinica:

- Bulk upload using OC GUI
 - Inflexible
- Pushing individual participant data to OC using APIs

OpenClinica APIs

- Are RESTful APIs with OAuth 2.0 authorisation protocol
 - Our web applications use the same
- Some notable APIs:
 - to get a case report form for a participant
 - to register a new participant
 - to create a new event for a participant:
- Our software that uses these APIs:
 - Applications developed in Java using Spring Boot framework
 - RESTful web services using the same technology
 - Bash scripts and C++ programs in the back end

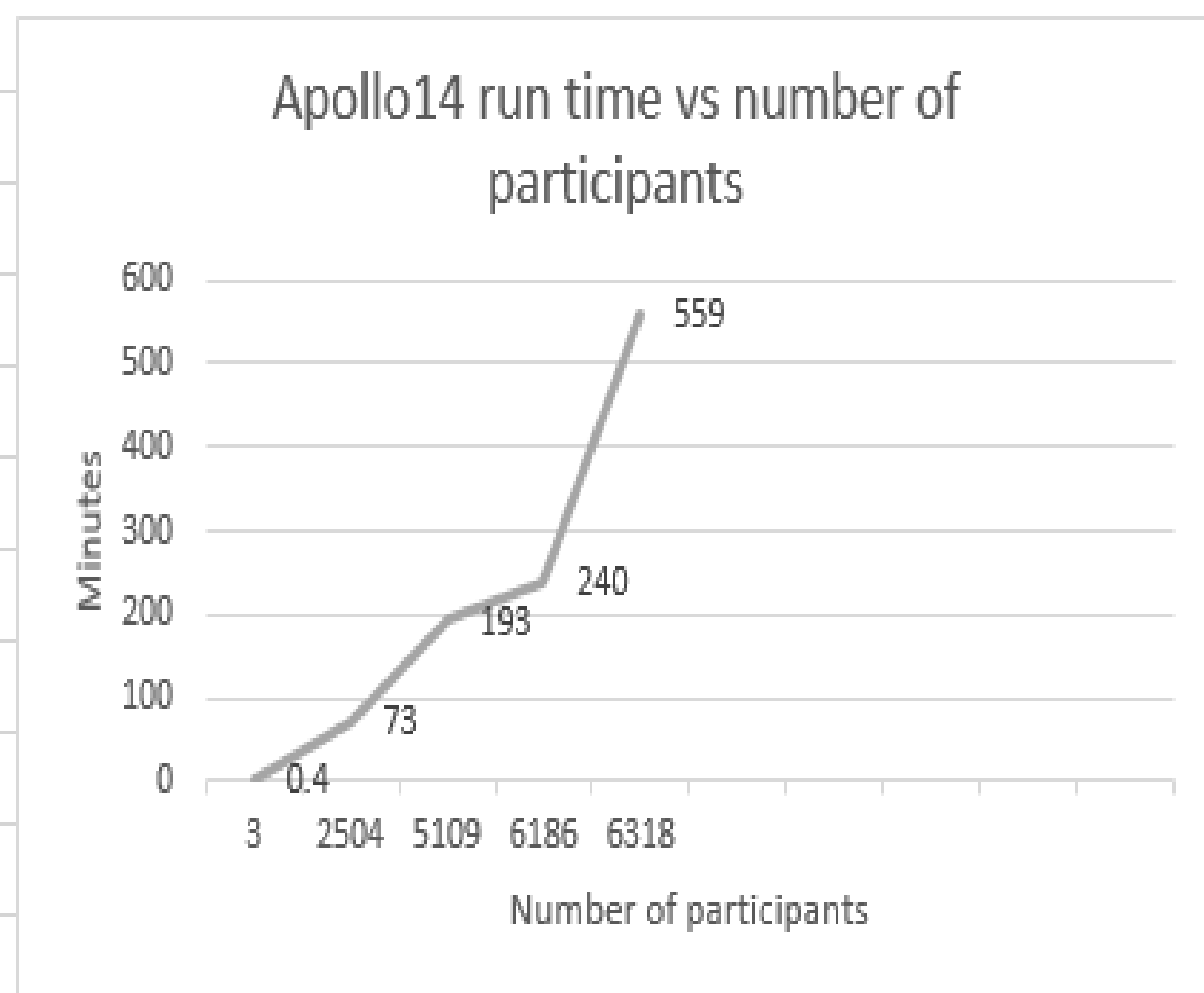
How we planned to use the APIs

- Apollo12
 - Upload newly registered participants
 - Update status of existing participants
- Apollo14:
 - Download all the clinical data for all the participants every night

A problem !

Time Apollo14 took to download clinical data in test environment

date	participants	time (minutes)
23-Jan	3	0.4
30-Jan	2504	73
15-Feb	5109	193
25-Feb	6186	240
13-Apr	6318	559



A combination of OpenClinica data download and Insight data download

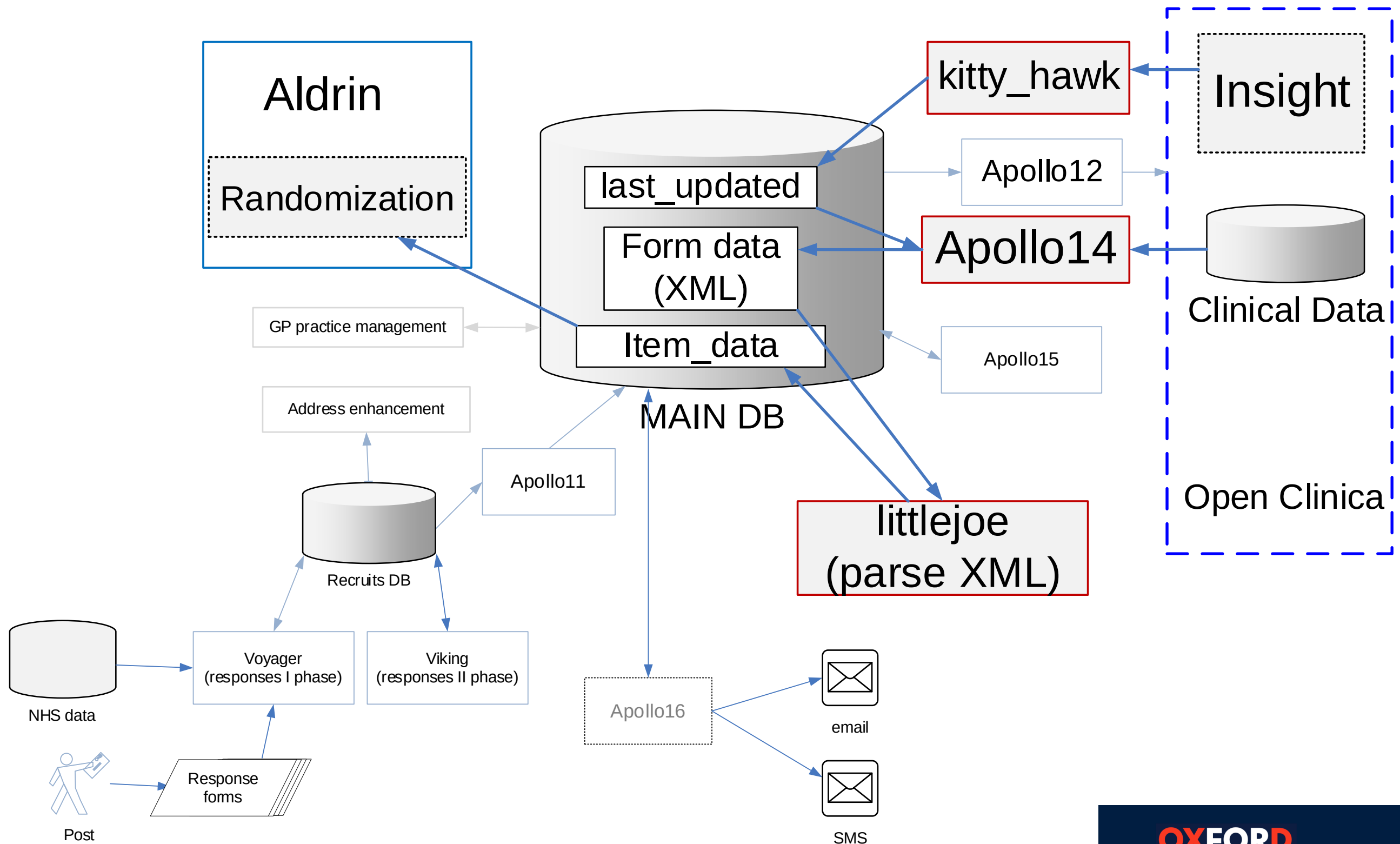
- Target OC download to only download data for participants whose data has changed
- Use Insight, the reporting module, to obtain the information about the last update time for a participant
- Develop a program to download data from this report using Insight APIs and place the data in the main database – *KittyHawk*
- Amend Apollo14 to only download data for those participants where there was an update

Handling downloaded OpenClinica data – further improvements

- A new program – LittleJoe – complete clinical data parse and storage in the main database because:
 - OpenClinica data was in XML format
 - Apollo14 was extracting from the XML document only a portion of the OpenClinica data
 - The in-house software needed more and more of the OpenClinica data

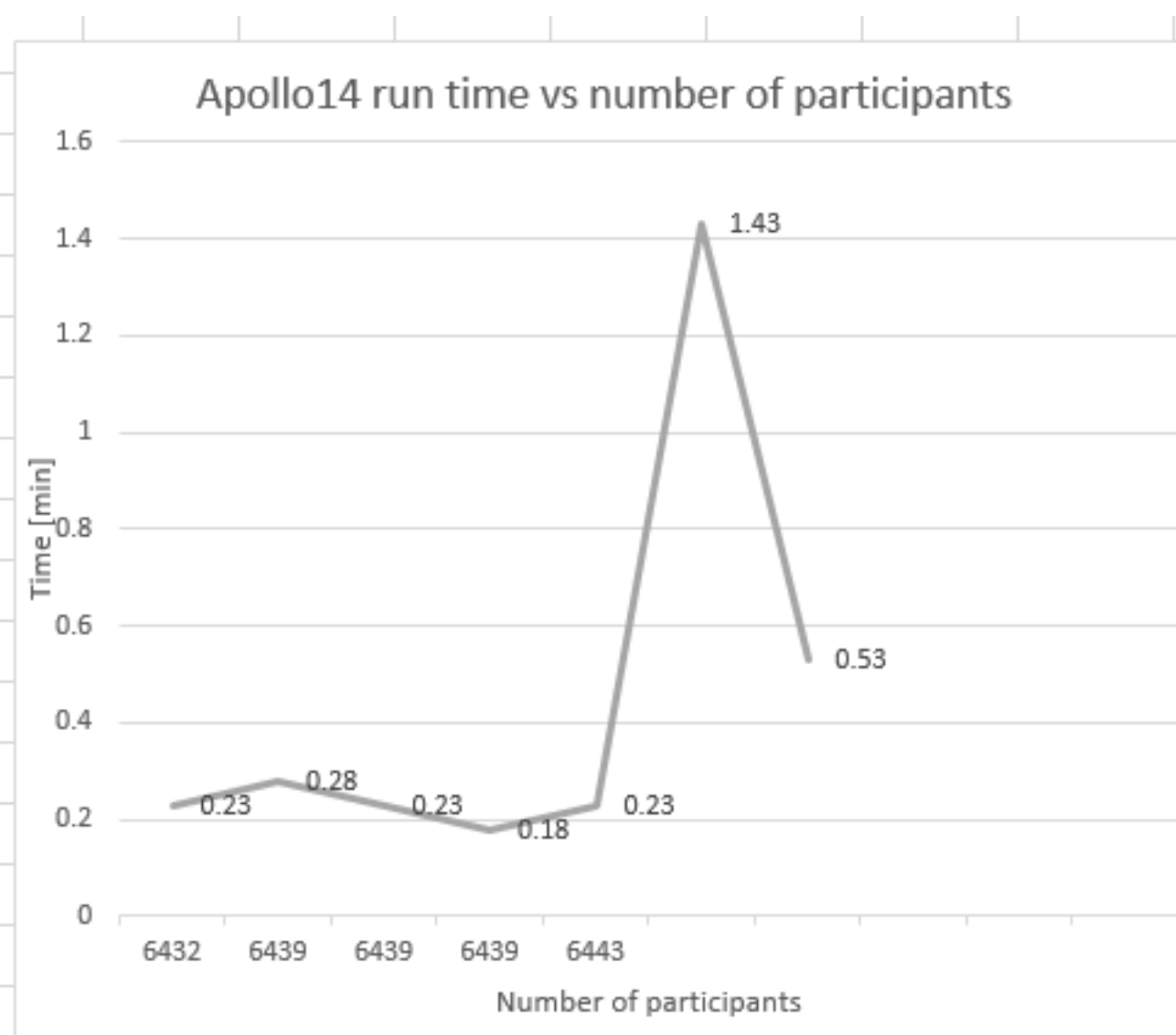
The updated diagram of the system

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Times Apollo14 took to download clinical data in the new system

date	participants	time (minutes)
17-Apr	6432	0.23
27-Apr	6439	0.28
02-May	6439	0.23
17-May	6439	0.18
01-Jun	6443	0.23
09-Jun	6454	1.43
22-Jun	6509	0.53



Summary

- Off-the-shelf clinical trials software increases the speed of the software delivery
- But, there might be areas where additional components are needed
- Complementing OpenClinica with our in-house software brought the desired functionality
- The problems have been overcome, but the system is still under development and we might yet find areas for further improvements

References

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THANK YOU

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