

OPENCLINICA CASE STUDY

# Zero Disruptions: Migrating 14 Mid-Study Clinical Trials in 16 Months

In Collaboration with **Imperial College  
London**



## Background

Formed in 1907, Imperial College London (Imperial) is home to the greatest concentration of high impact research of any major United Kingdom (UK) university and is fourth in the UK for world-leading research. Approximately 91 percent of their research activity has been judged as world-leading or internationally excellent, the highest proportion of all UK universities.

## Challenge

Imperial wanted to modernize its electronic data capture (EDC) system to ease user burden, reduce training and data management challenges, streamline processes, and decrease costs. Historically, the only practical way to migrate from one system to another was to maintain ongoing studies in the existing system while starting new studies in the new system. However, Imperial had several long-term ongoing studies and did not want to bear the added expense and administrative burden associated with maintaining two systems.

Imperial decided to leverage OpenClinica's proven process to migrate 14 ongoing studies from its legacy system onto the OpenClinica platform which included their core EDC, Participate (ePRO), Insight (reporting), and Randomize.

### Key considerations for Imperial

- Maintain uninterrupted regulatory compliance during data migrations
- Deliver minimal disruption to study staff, patients, and clinical leaders
- Manage multiple studies with varying data structures and system functionality
- Match differing data structures and system functionalities across multiple studies
- Address unplanned resource changes effectively
- Ensure a seamless cutover by the April 2023 deadline
- Position the studies for continued success on the OpenClinica platform



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**OpenClinica is as passionate and as invested in Imperial's success as we are.**

Amanda Bravery, Head of Clinical Data Operations, Imperial College London



# Solution

As experts in processing clinical trial data and interoperability, OpenClinica applied a rigorous process to ensure both high quality and on-time delivery.

Key components of the data migration process included



## Data Migration Readiness Checklist: Are You Ready?

### Testing & Validation

- Ensure training of UAT participants
- Create test plans in advance
- Align organizational SOP requirements

### Data Targets

- Identify data points for migration
- Determine how to handle open queries
- Identify exclusions to consider

### Team Definition

- Include members of clinical operations, data management, IT, biostatistics, quality assurance
- Identify roles and responsibilities across and within departments

### Study Assessment & Identification

- Identify studies that will not lock within the next six months
- Identify additional integration needs for each study (such as randomization, eConsent, ePRO and reporting)

### Documentation Needs

- Review and update all existing SOPs
- Reuse processes and identify new work instructions
- Update data management plan and eCRF completion guidelines

### Training

- Create training plan upfront
- Identify audience
- Outline training scope
- Determine training delivery and materials including in-person, virtual, on-demand, slides, and reference guides.

Mid-study data migrations are inherently complex, since any two systems will have different ways of storing and structuring data, and different interfaces for adding, editing, and reviewing the data. To contend with the complexity of migration, OpenClinica, in close collaboration with Imperial, emphasized migration readiness and managed a rigorous, eight-step process for each of the 14 studies:

- 1 Plan
- 2 Database Design
- 3 Data Mapping
- 4 Migration Script Development
- 5 Script Validation and Sandbox Checks
- 6 Test Migration
- 7 Production Migration
- 8 Final Report

To mitigate risk, the project teams adopted an iterative approach, migrating one study at a time before moving to batch migrations. This allowed them to refine the process for each subsequent study.

Furthermore, OpenClinica utilized its platform's extensive data import capabilities and drew from prior experience. Notably, a comparable project involved the successful migration of five ongoing studies within a six-month period for a Top 25 biopharma company.



OpenClinica minimized study staff disruptions and maintained regulatory compliance throughout the process.

Amanda Bravery, Head of Clinical Data Operations, Imperial College London

## Migration Timeline





## Results

OpenClinica successfully migrated 14 active studies – with 1,700+ patients and 150,000+ forms – during a 16-month timeframe onto the OpenClinica platform. During this time, any study was offline for no more than three days and not a single data point was dropped. Successfully completed one week ahead of the April 2023 deadline, the mid-study data migrations allowed Imperial to streamline their day-to-day operations, improve the user experience for clinicians and participants, and better manage their vendor portfolio and associated costs.

“ OpenClinica is as passionate and as invested in Imperial’s success as we are. Given the thoroughness of their data migration process, I - and our site leaders - are confident that ALL of our study data was migrated during the seamless cutover. Just as importantly, OpenClinica minimized study staff disruptions and maintained regulatory compliance throughout the process.

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Amanda Bravery, Head of Clinical Data Operations, Imperial College London

## Imperial College London

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Imperial College London is a world top ten university with an international reputation for excellence in teaching and research. Consistently rated amongst the world's best universities, Imperial is committed to developing the next generation of researchers, scientists and academics through collaboration across disciplines. Located in the heart of London, Imperial is a multidisciplinary space for education, research, translation and commercialisation, harnessing science and innovation to tackle global challenges. For more information, please visit <https://www.imperial.ac.uk/>

## OpenClinica

Since 2006, OpenClinica has advanced clinical trial research by delivering innovative and practical technologies. Our commitment to pushing boundaries continues with our cloud-based platform which streamlines and simplifies source data acquisition and workflows through automation. OpenClinica serves as a secure bridge between healthcare and research, and is the trusted choice for leading life science companies, esteemed academic institutions and government entities worldwide.

We take great pride in supporting a diverse array of organizations ranging from small startups to large institutions across biotechnology, pharmaceutical, academic, device manufacturing and contract research sectors. Our software has supported over 20,000 studies, impacting more than five million patients.

To talk about your data migration needs or for a demo of our platform, reach out:

Contact Us 