

Digitalisation of Clinical Trials⁺



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The Royal Marsden & Clinical Research

- Founded in 1851 - the first centre in the world dedicated to the study and treatment of cancer
- With the Institute Of Cancer Research (ICR), the only Biomedical Research Centre (BRC) dedicated specifically to cancer in the UK and one of the top 4 cancer centres in the world
- Around 600 clinical studies open at any one time, with about 170 new studies opened each year, including academic and commercial studies
- 400 FTE staff across 3 clinical trial units:
 - 3 locations: London, Sutton and Kingston
 - Studies involving multiple clinical units
- Carry out all types of clinical research, e.g. drug studies, surgery, radiotherapy, imaging, tissues, qualitative, data ...

Our Strategic Objectives



Research Is a Paper heavy process



The Oak Cancer Centre



The RMH Green Plan

Development Approach

➤ Cross disciplinary Project team



➤ Hyland and RMH Partnership

Hyland™

➤ DIA TMF Reference Model

DIA Trial Master File
Reference Model

End Result : Live & Operational

- New system built that meets the requirements of clinical research regulators
 - ✓ Role-base access, limited by studies
 - ✓ Restricted access to some folders
 - ✓ Person folder to store training information
 - ✓ Clear folder structure and naming of documents
 - ✓ Flexible use of DIA eTMF Reference Model
 - ✓ QC workflow
 - ✓ Document retrieval and custom queries
 - ✓ Audit trail and reporting
 - ✓ Electronic archiving

End Result : Live & Operational

- The eTFM- eISF also enables and ensures
 - ✓ Coordination of studies across multiple location, multiple clinical units
 - ✓ Remote working, remote monitoring and auditing
 - ✓ Completeness, quality and timeliness of TMF/ISF
- Improves the quality of studies run at the Royal Marsden and ICR, to support the development of new treatments for cancer patients

Final Remarks

- Closing comments from Lisa...