

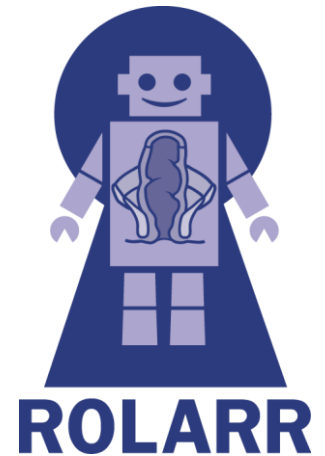
Successful Navigation Through The Challenges Of International Trial Set Up

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ROLARR Trial: RObotic versus LAparoscopic Resection for Rectal Cancer

UK government funded trial (NIHR EME Programme)

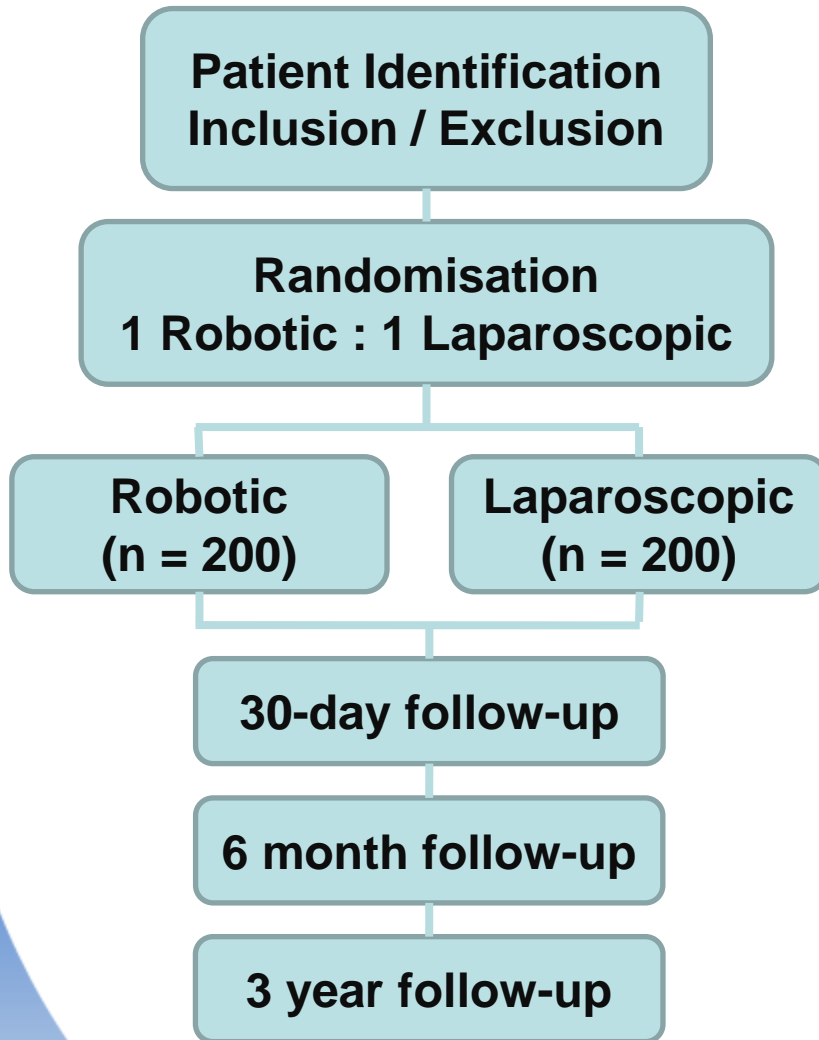


Aims

- To perform a rigorous evaluation of robotic-assisted rectal cancer surgery
- To compare with laparoscopic surgery
- Short- and long-term outcomes
 - Technical
 - Oncological
 - Functional
 - Quality of Life
 - Healthcare economics



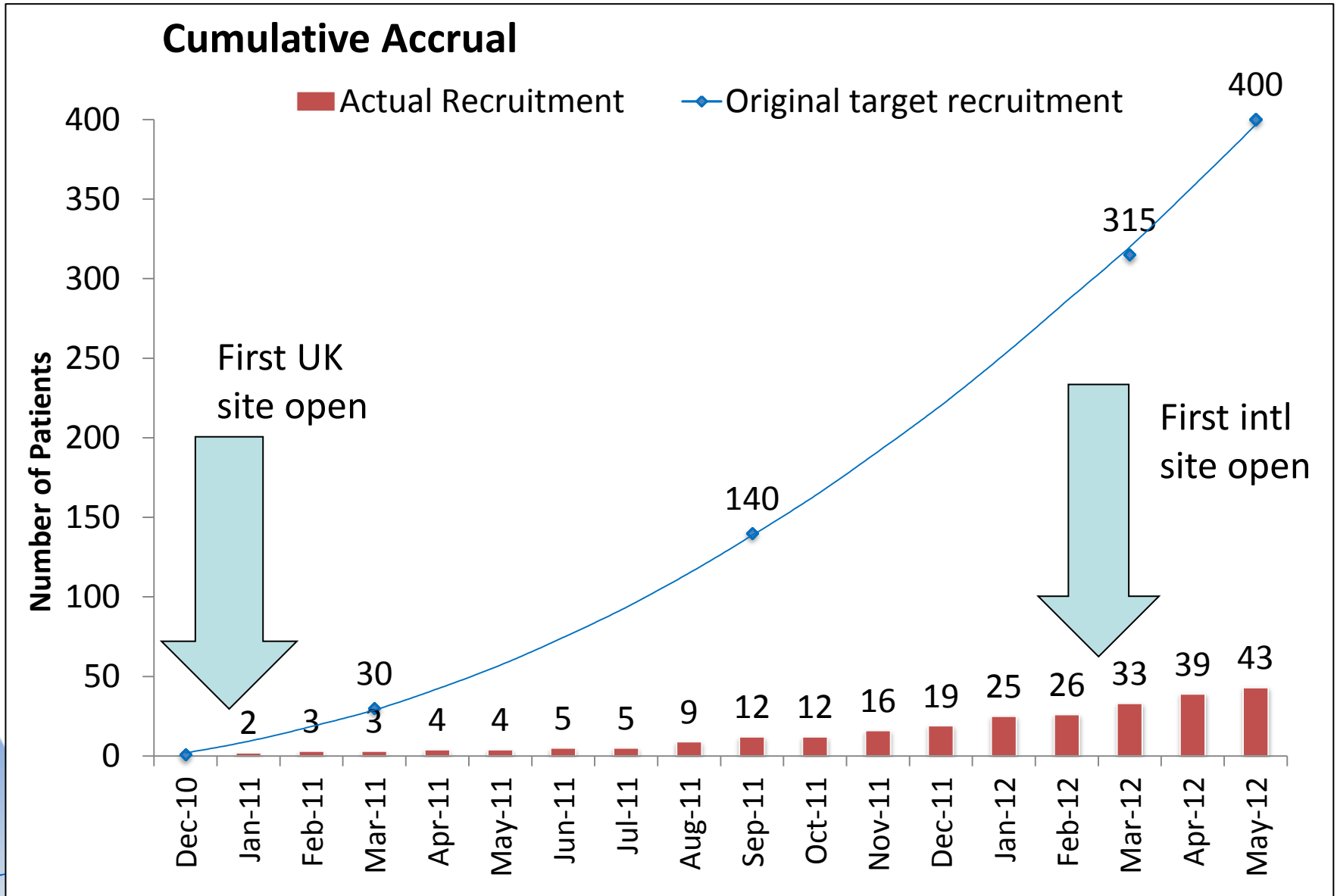
ROLARR Trial*



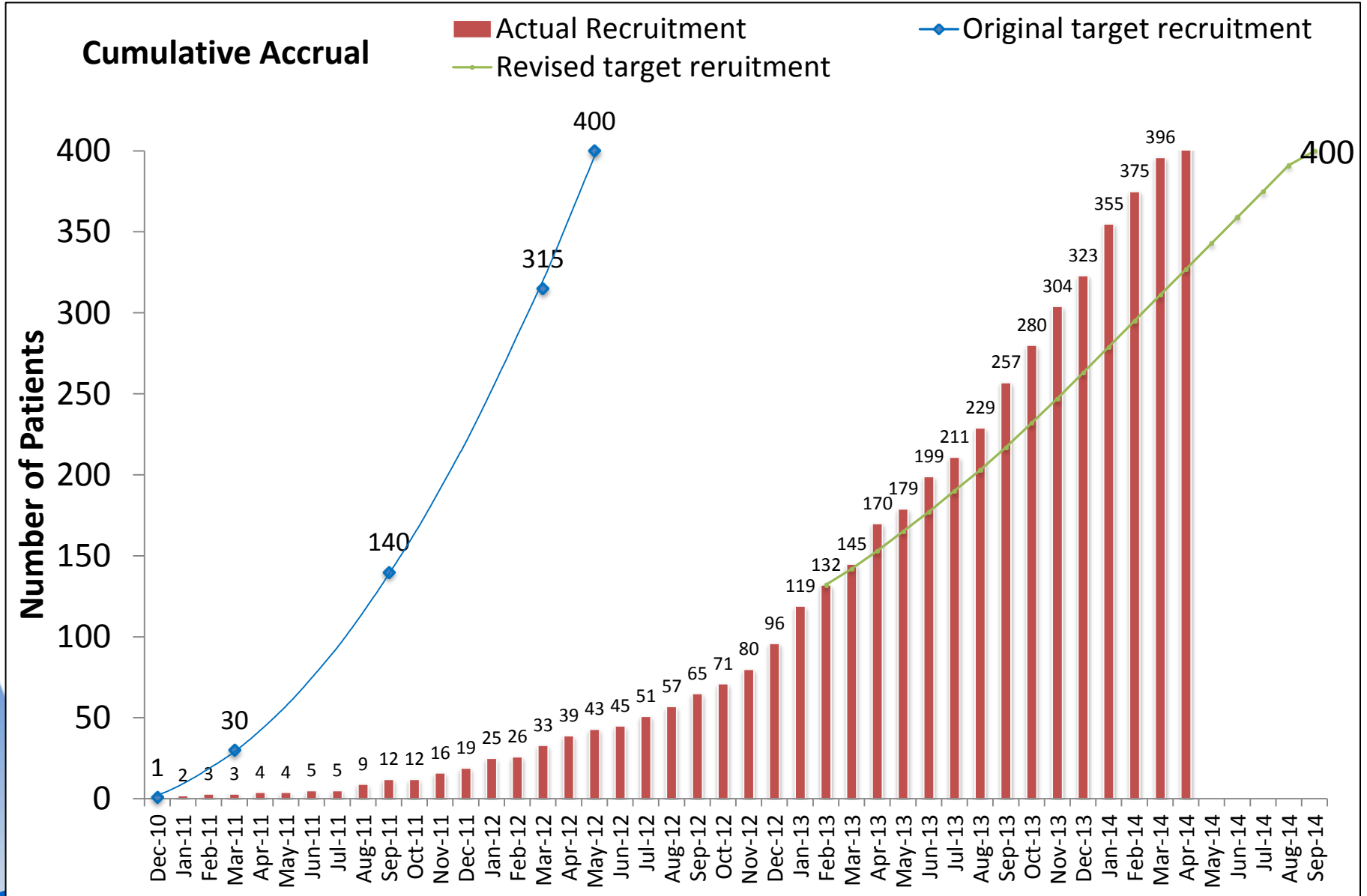
- Surgical trial
- Requirement for international sites
- Simple design
- Pragmatic
- English protocol and trial documents
- Translated patient documents

*This project was awarded by the Efficacy and Mechanism Evaluation (EME) programme, and is funded by the Medical Research Council (MRC) and managed by the National Institute for Health Research (NIHR) on behalf of the MRC-NIHR partnership.

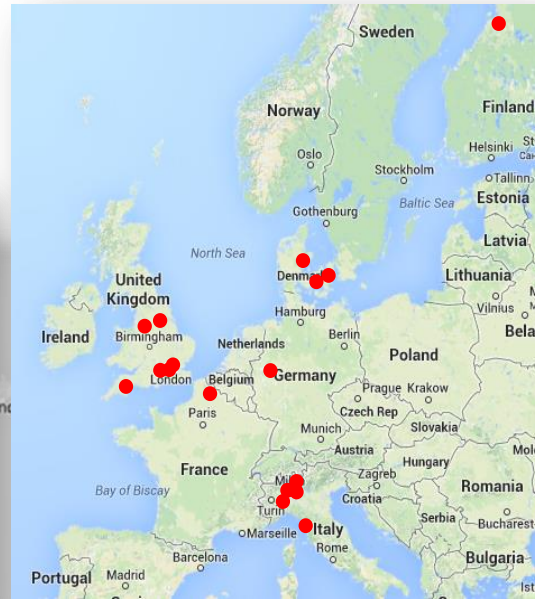
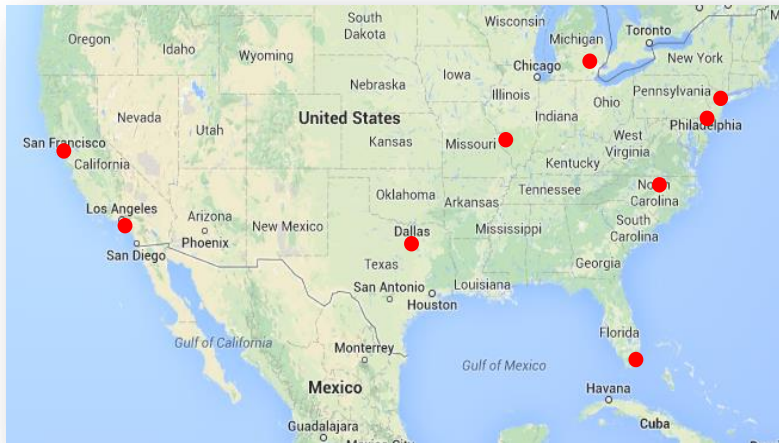
Original planned timelines



Current Recruitment



ROLARR Sites



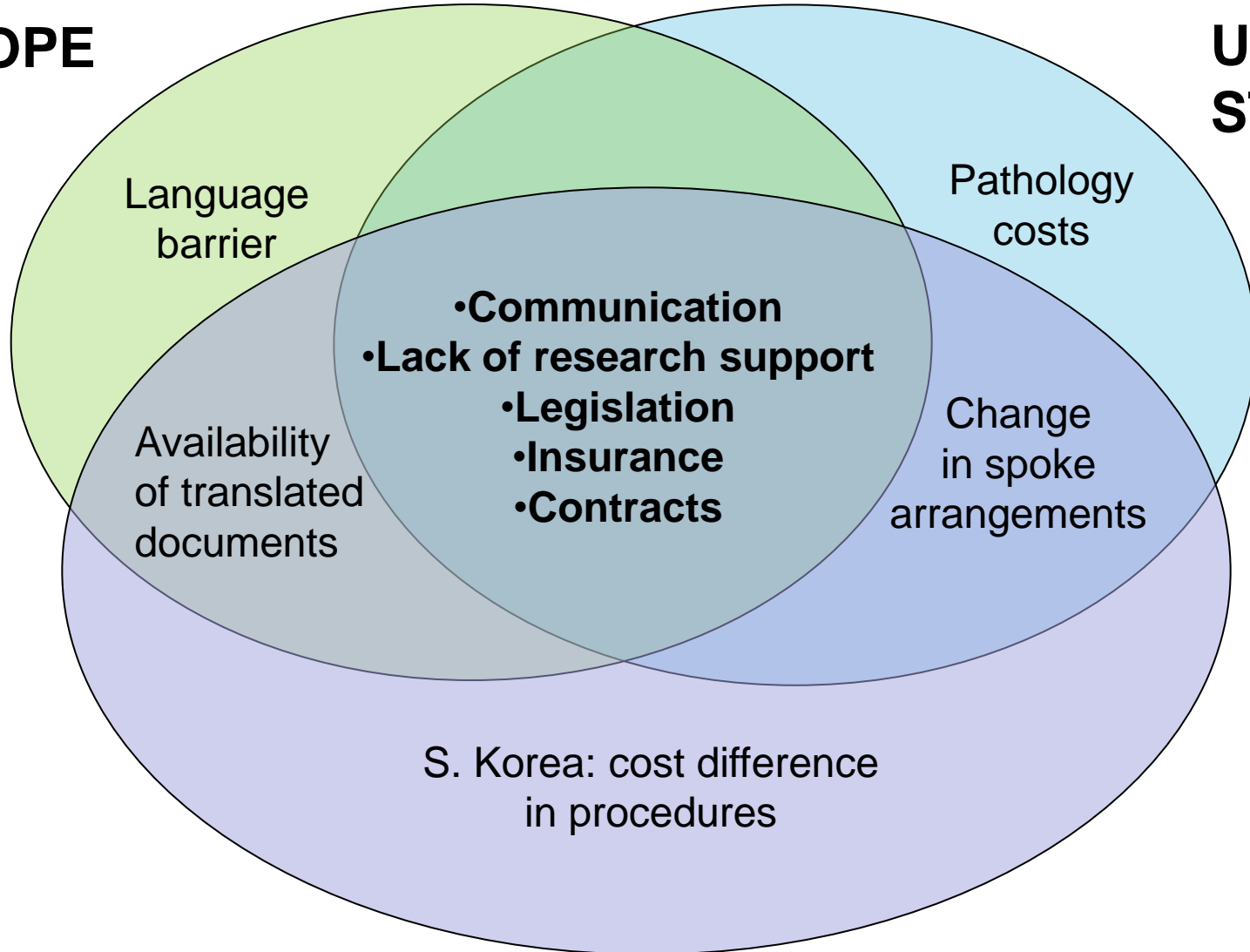
South Pacific Ocean

South Atlantic Ocean

Complexities of International Site Set-up

EUROPE

UNITED STATES

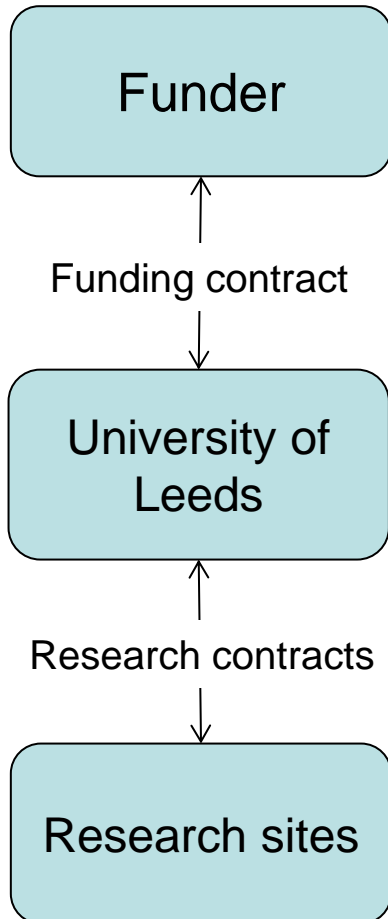


ASIA

Trial Insurance

- Pragmatic trial
 - Participants require an operation
 - Whilst participant's are randomised, it is the surgeon's responsibility to assess eligibility for trial
 - Both procedures in the trial to be carried out as per surgeon's normal practice
- Considered to be a low risk trial
- Insurance taken out on a country by country basis for coverage of the protocol risk only.
 - Only covers injury due to negligence in the design of protocol
 - Requires indemnification from research sites from negligence on their part

Contracts & Insurance

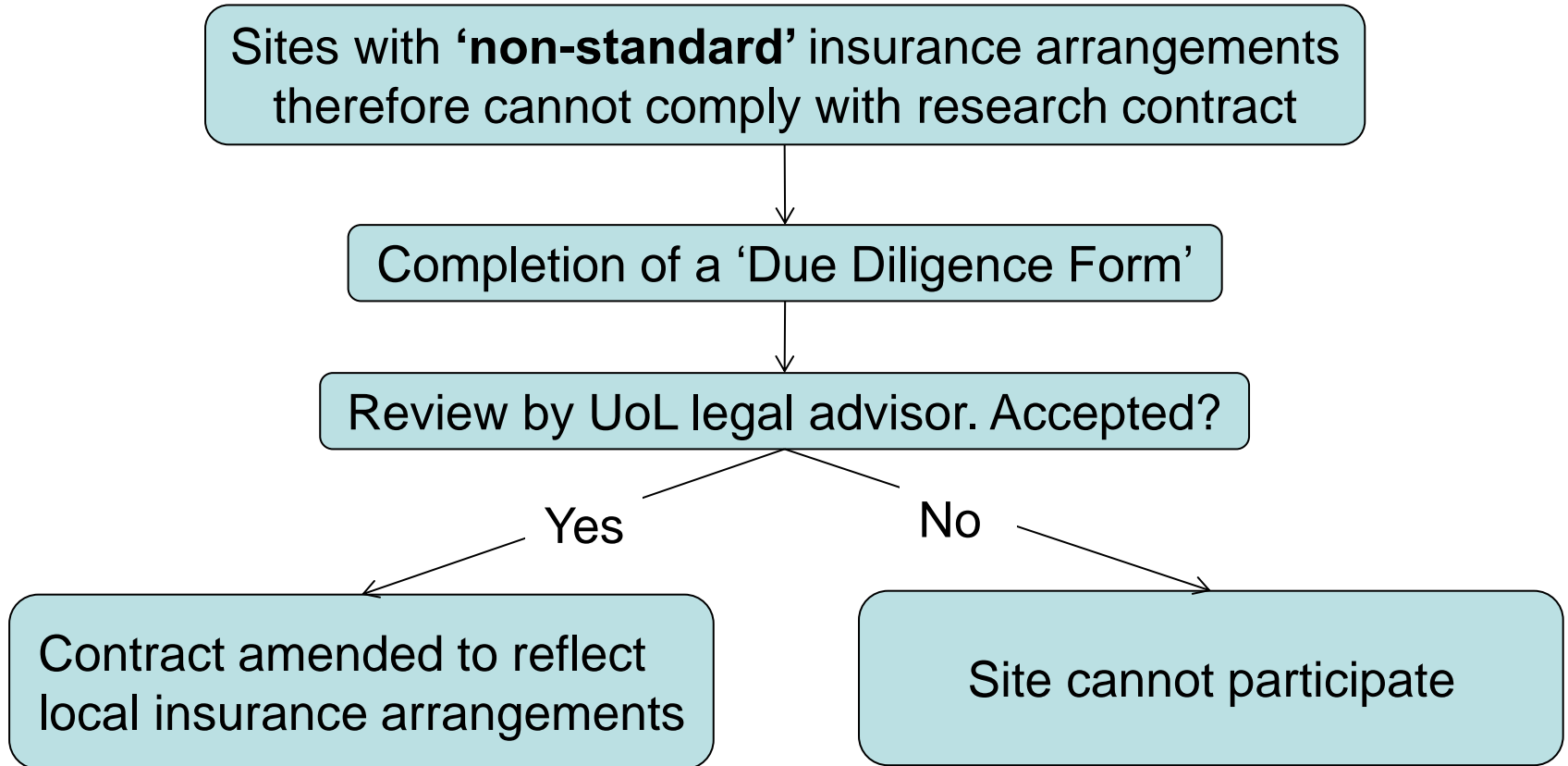


- Funding contract between the funder and University of Leeds
- Certain obligations to be filtered down to sub contracts i.e. contracts with research sites
- Establishing appropriate insurance arrangements was a primary cause of delay in contract sign-off

‘Non-standard’ insurance arrangements encountered:

- Self insurance
- Low insurance limits
- Nationwide coverage

Contracts & Insurance



Risk based process ensuring adequate and robust protection is available for participants

Recommendations

- Simple, clear and 'essentials only' protocol, CRFs and patient documents
- Involvement of collaborative parties
- Start contract negotiations early
- Site payments
- Budget for contingency visits/ investigator meetings
- Realistic timelines

Thank you

Any questions?