Progress Review

Investigator Meeting

1st May 2015, University of Birmingham Medical School

BIRMINGHAM CLINICAL TRIALS UNIT

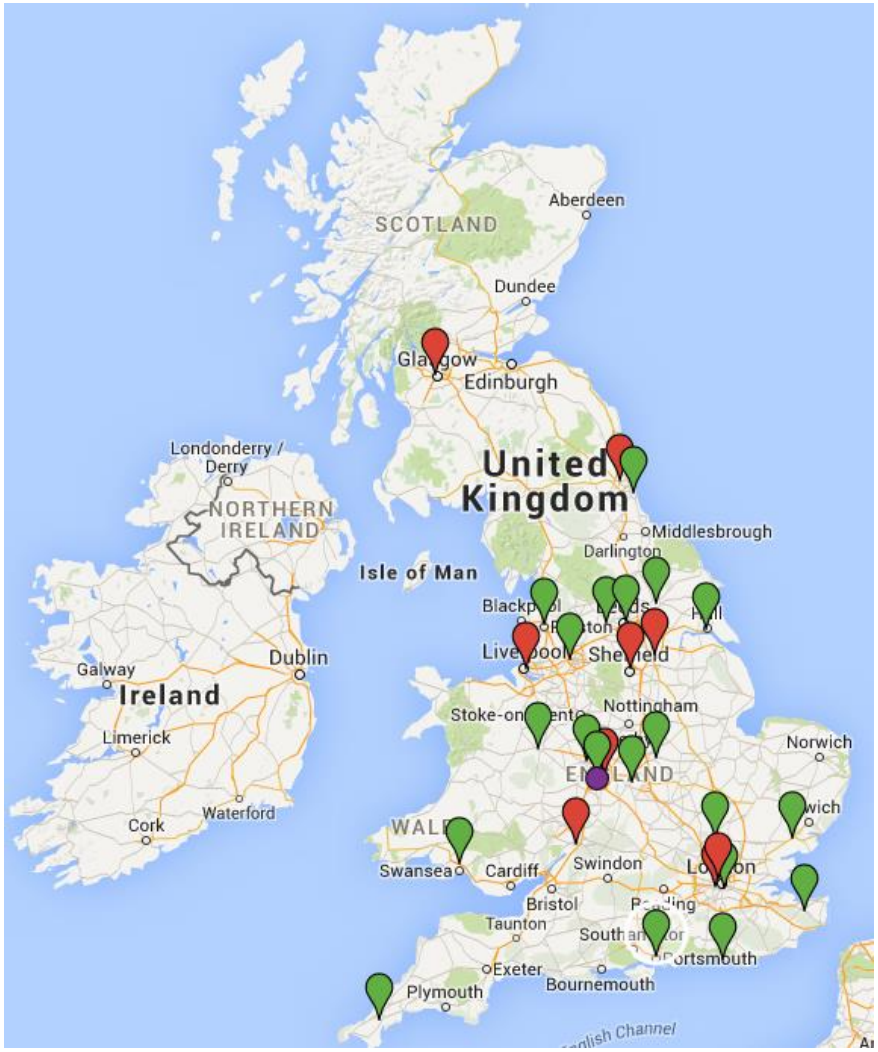
UNIVERSITY OF BIRMINGHAM

Hull and East Yorkshire Hospitals NHS Trust

NHS

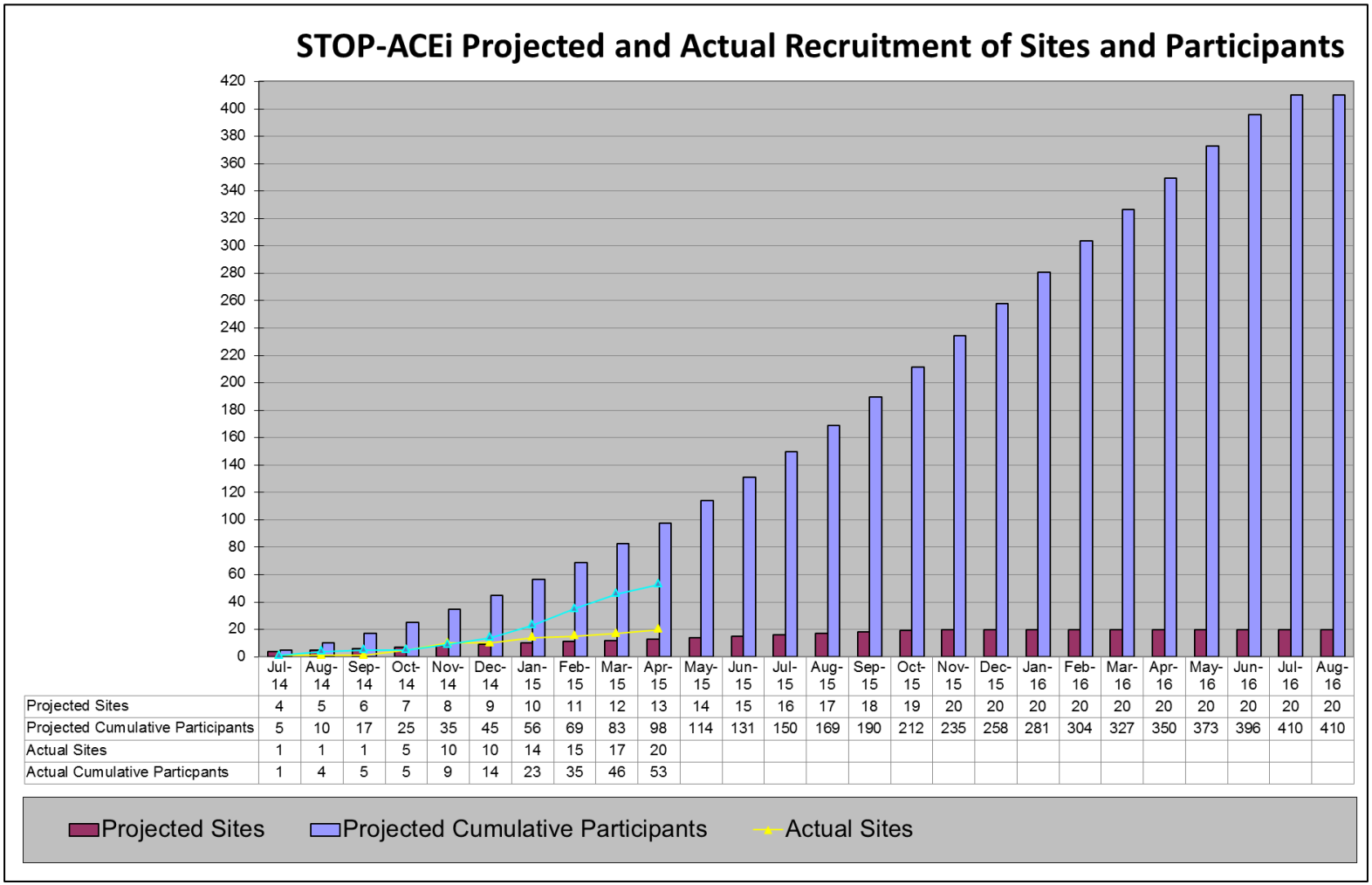
Sites

- 30 secondary care sites total
- 20 sites are open to patient recruitment
- 4 lead sites involved in trial management
- Open to new sites joining



Recruitment

- Recruitment target: 410 patients
- Recruitment due to finish end of Jul 2016



	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15	Nov-15	Dec-15	Jan-16	Feb-16	Mar-16	Apr-16	May-16	Jun-16	Jul-16	Aug-16
Projected Sites	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	20	20	20	20	20	20	20	20	20
Projected Cumulative Participants	5	10	17	25	35	45	56	69	83	98	114	131	150	169	190	212	235	258	281	304	327	350	373	396	410	410
Actual Sites	1	1	1	5	10	10	14	15	17	20																
Actual Cumulative Particpants	1	4	5	5	9	14	23	35	46	53																

Recruitment

- 2363 patients screened
- 140 potential patients to approach identified
- Top reported reasons for ineligibility
  - Not on ACEi/ARB
  - CKD not stage 4 or 5
  - eGFR decline <2mL/min/1.72m^2 per year
  - 'Other'
  - On dialysis or had transplant

Completing screening & approach logs

v1.1, 22 Sep 2014

STOP-ACEi screening log

Site Name:

Site Prinicpal Investigator:

Clinic date / Screening date	Total pts at clinic / screened	Under 18	Not CKD 4-5	On dialysis/ had transplant	Not on ACEi/ARB	On ACEi/ARB <6months	BP too high or not controlled	<3 months specialist f/up	MI or stroke in last 3 months	Poor prognosis/ projected survival	eGFR decline <2 mL/ min/ year	Other (give details)	Unsuitable	To follow-up later	To approach	Pts not screened	Further details if other
5/3/15	20	0	10	1	5	0	2	0	0	0	1	0	19	0	1	0	
12/3/15	21	0	8	2	8	0	0	0	1	0	2	0	21	0	0	0	
19/3/15	18	0	12	0	3	0	1	0	0	1	0	0	17	0	1	0	
26/3/15	17	0	5	1	7	1	1	0	0	0	1	1	16	0	1	0	Frequent DNAs
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Totals:	76	0	35	4	23	1	4	0	1	1	4	1	73	0	3	0	

Reasons unsuitable if 'other'

Can screen an upcoming clinic or can do a larger screen of electronic records

Give 1 reason per patient

No of unsuitable should equal the total of all reasons unsuitable in the white columns

Unsuitable +
To follow-up +
To approach
= Total patients screened

Please approach all suitable patients

Completing screening & approach logs

- Completed for eligible patients that receive patient information only.

Codes

A. Recruited into STOP-ACEi	**E.** Patient declined because concerned about trial intervention
B. Not eligible / error when screening. Please specify failed criterion.	**F.** Patient declined, but no reason given
C. Patient declined because not interested in research/STOP-ACEi	**G.** Other (please specify)
D. Patient declined because visit assessments will take too long	

	Patient Initials	Patient DoB	Hospital Number	Date of screening (dd/mmm/yyyy)	Date PIS sent/given (dd/mmm/yyyy)	START code on PIS	Code/s see list on page 1	Further details	Study number (if recruited)
1.	[redacted]	[redacted]	[redacted]	05 MAR 15	05 MAR 15		A		1012
2.	[redacted]	[redacted]	[redacted]	19 MAR 15	19 MAR 15		A	No extra biomarker samples	1310
3.	[redacted]	[redacted]	[redacted]	26 Mar 15	26 Mar 15		E	Concerned about BP	
4.									

Don't share PII with BCTU

START codes not in use

Enter code for all entries

Enter trial ID if they go into the study

Amendments

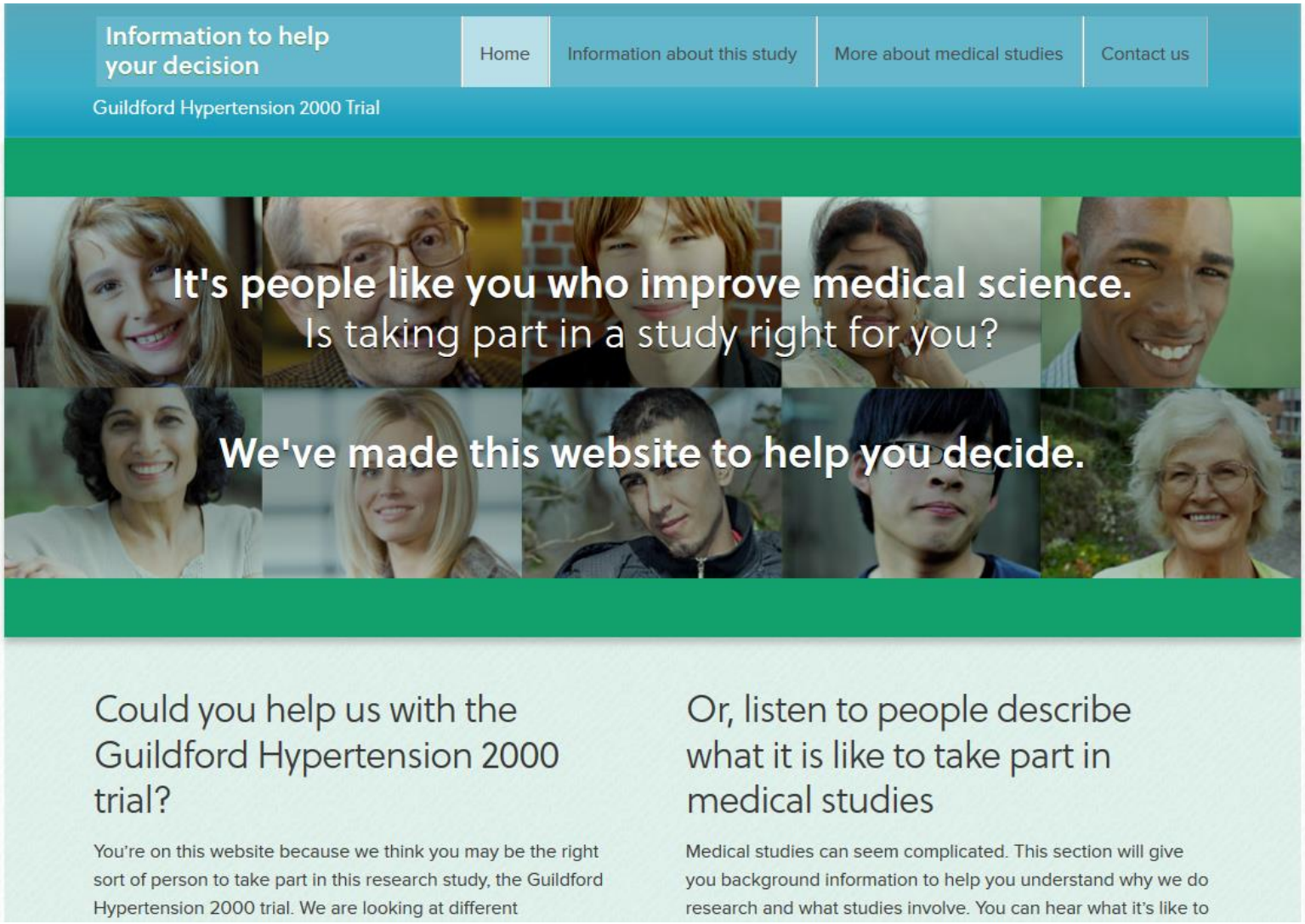
No.	Changes	Approved / Implemented
NSA	Error correction on ICF	07-Feb-2014
SA01	Minor clarifications to protocol wording New sites and PI changes	30-May-2014
SA02	New sites and PI changes	25-Sep-2014
SA03	New sites and PI changes	11-Dec-2014
SA04	Addition of MRC START sub-study	Approved 09-Mar-2015, Not yet implemented

MRC START project

- **S**ystematic **T**echniques for **A**ssisting **R**ecruitment to **T**rials

- Researching recruitment interventions to improve patient recruitment
- Nested into existing RCTs, including STOP-ACEi
- MRC in STOP-ACEi
  - Multimedia resource to provide patients with information
- http://www.population-health.manchester.ac.uk/mrcstart/STARTInterventions/MM/

MRC START - Multimedia intervention



MRC START - Multimedia intervention

Why are we doing the study and why do we need your help? | What will happen during the study? | Questions and Answers | Study care and safety | What happens after the study?

Lead researcher, Chris Fife-Schaw, talks about the study.
Hear David's story, a previous participant, at the bottom of the page

Why is this study important?

People need to do exercise to stay healthy and all the research shows that being active, even if it is just a little bit active, is better than doing nothing at all. Exercise not only helps you stay fit but it helps you keep your weight down, improves the health of your heart and lungs and is even thought to help alleviate depression and delay the onset of dementia in older people. Currently GPs can refer people for exercise as a kind of treatment and this trial is trying to work out what kinds of exercise programme are most effective in helping people adopt and maintain an active lifestyle.

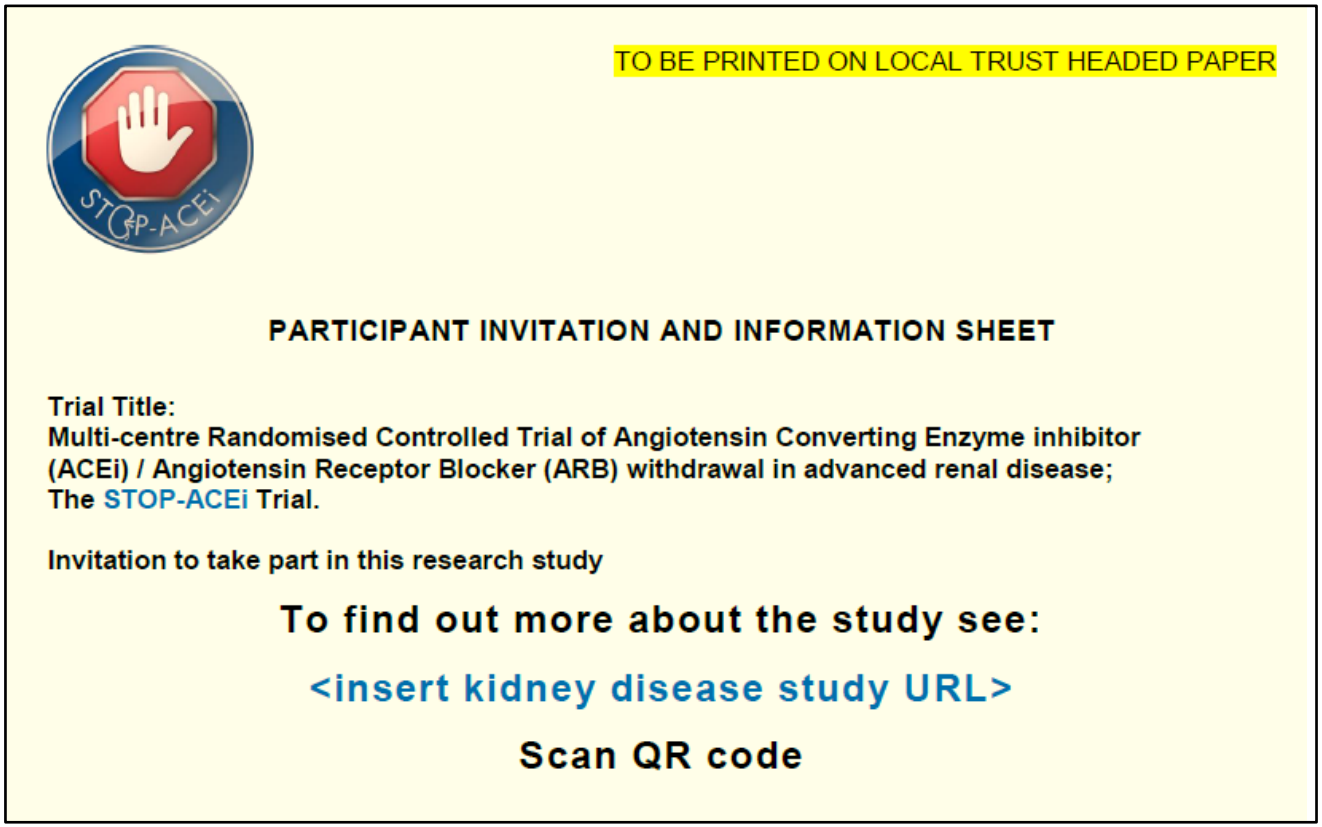
Why we need your help.

We need to study people whose GPs think that they would benefit from a programme of exercise. **We are interested in people who:**

- Are aged 18 to 74 years at the start of the trial.
- Have been diagnosed as having hypertension, suspected hypertension and pre-hypertension.
- Are screened as being 'inactive' or 'moderately inactive' on the GPPAQ – this is a short self-completion questionnaire that we send you.
- Have access to the internet and an e-mail account.
- Are able to understand the Informed Consent Form, and understand study procedures.
- Have signed the consent form.

MRC START in STOP-ACEi

- Website link added to the PIS and invitation letter
- Changes for half of sites according to a randomisation at BCTU.



TO BE PRINTED ON LOCAL TRUST HEADED PAPER

PARTICIPANT INVITATION AND INFORMATION SHEET

Trial Title:
Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease; The STOP-ACEi Trial.

Invitation to take part in this research study

To find out more about the study see:

<insert kidney disease study URL>

Scan QR code

Learning from experience

- Eligibility queries
  - Immune-mediated renal disease
  - Blood pressure at randomisation
  - 5 or more BP agents
  - Ability to do 6-minute walk test

Learning from experience

- Withdrawal is when consent is withdrawn
  - Can withdraw consent from treatment, but continue follow-up – Intention to Treat principle
  - Ideally follow-up as per protocol, but routine data if not
- Non-compliance
  - STOP arm: taking ACEi/ARB
  - Continue arm: stopping ACEi/ARB

Learning from experience

- Dialysis patients
  - Not withdrawn
  - Continue with follow-up as per Protocol
  - Trial assessments should be done BEFORE dialysis
- Communication with the GP
- Duration of baseline assessment
- Timing of randomisation – intervention must be after baseline assessments

Other STOP-ACEi Updates

- Protocol submitted for publication 
- Poster presentation at BRS 2015 in Leeds
- New site teleconferences 
- IT system update
- Protocol amendment for clarifications

Trial Oversight

- Trial Management Group
  - Day to day running of the trial
  - Meeting regularly
- Trial Steering Committee
  - Trial quality, credibility and progress
  - Last met 02 Mar 2015
- Data Monitoring and Ethics Committee
  - Patient safety and trial integrity
  - Last met 05 Feb 2015
- Funding body (EME)
  - Trial safety, progress and feasibility.
  - Reviewing annual reports and committee proposals

Trial Oversight

- Patient safety
  - No current concerns
  - No SARs reported to date
  - Most patients at early stage of intervention
- Trial Progress
  - Concerns for low patient recruitment
  - Impressed with level of interest from centres and number of sites
  - Research question still valid
  - No concerns for trial design, conduct or scientific integrity