Focussing on Recruitment

Investigator Meetings
1st and 2nd September 2016 – London and Leeds

UNIVERSITY OF BIRMINGHAM

BCTU Birmingham Clinical Trials Unit

Hull and East Yorkshire Hospitals
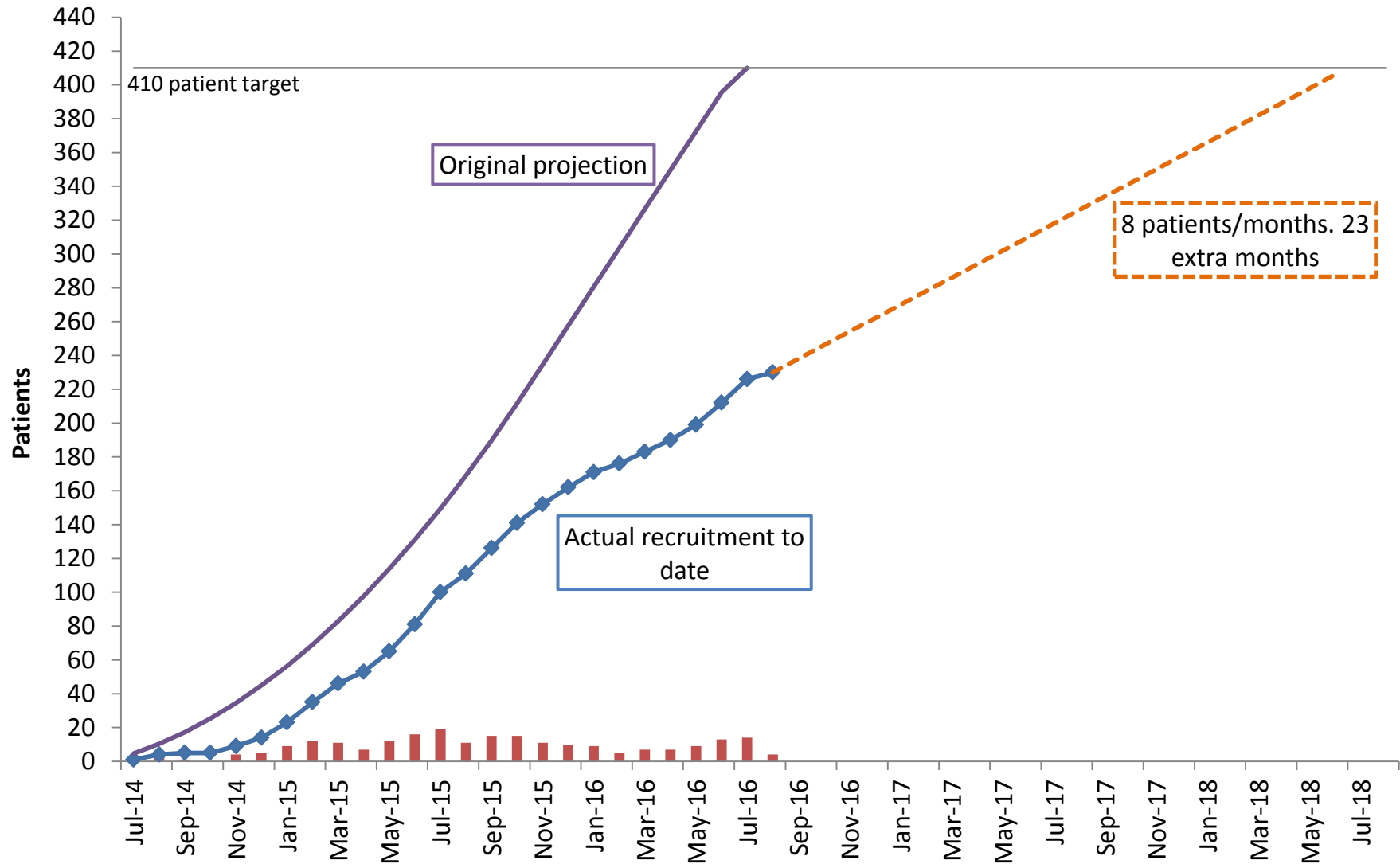NHS Trust

NHS
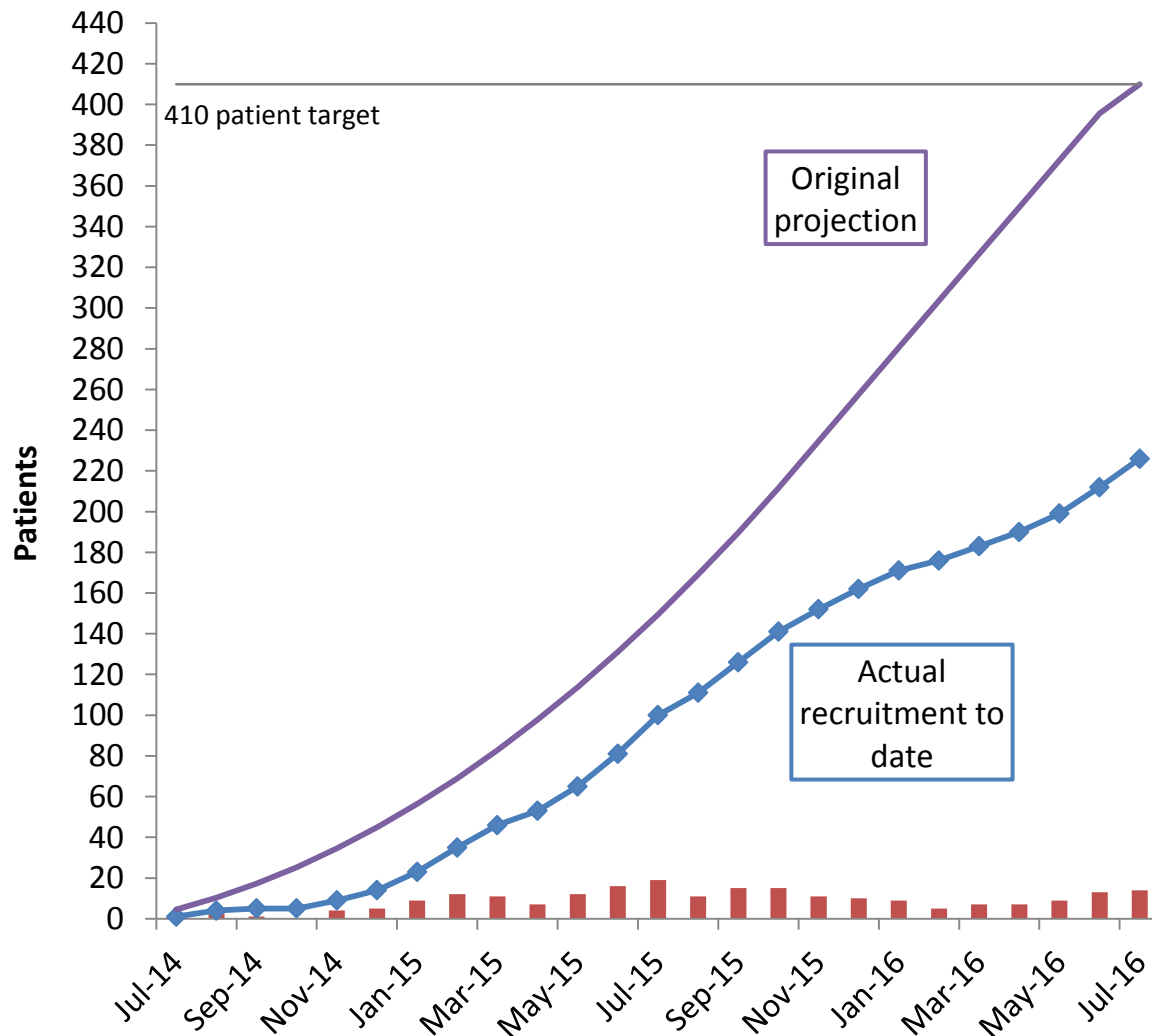
Recruitment

Original projection: 1.1 patient per site per month, opening 1 site each month up to 20 sites

Actual overall rate: 9 patients per month across 33 sites

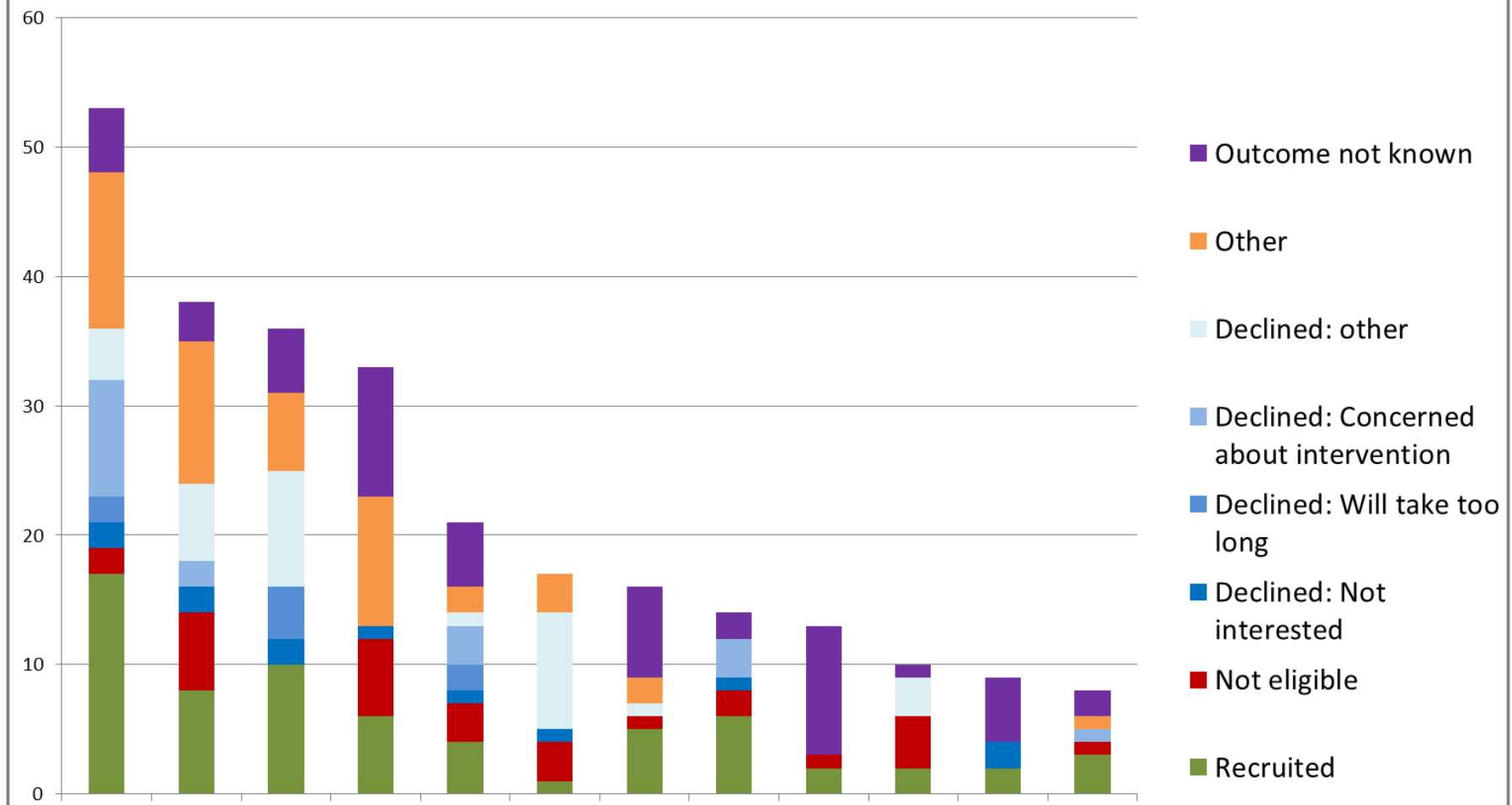Revised target in proposed extension: 8 patients per month = 2 more years

Recruitment

Recruitment – success rates

Graph showing recruitment outcomes for patients that are approached about participation in STOP-ACEi

Legend:
- Outcome not known
- Other
- Declined: other
- Declined: Concerned about intervention
- Declined: Will take too long
- Declined: Not interested
- Not eligible
- Recruited

Recruitment – obstacles

Chart showing reasons for non-participation where given
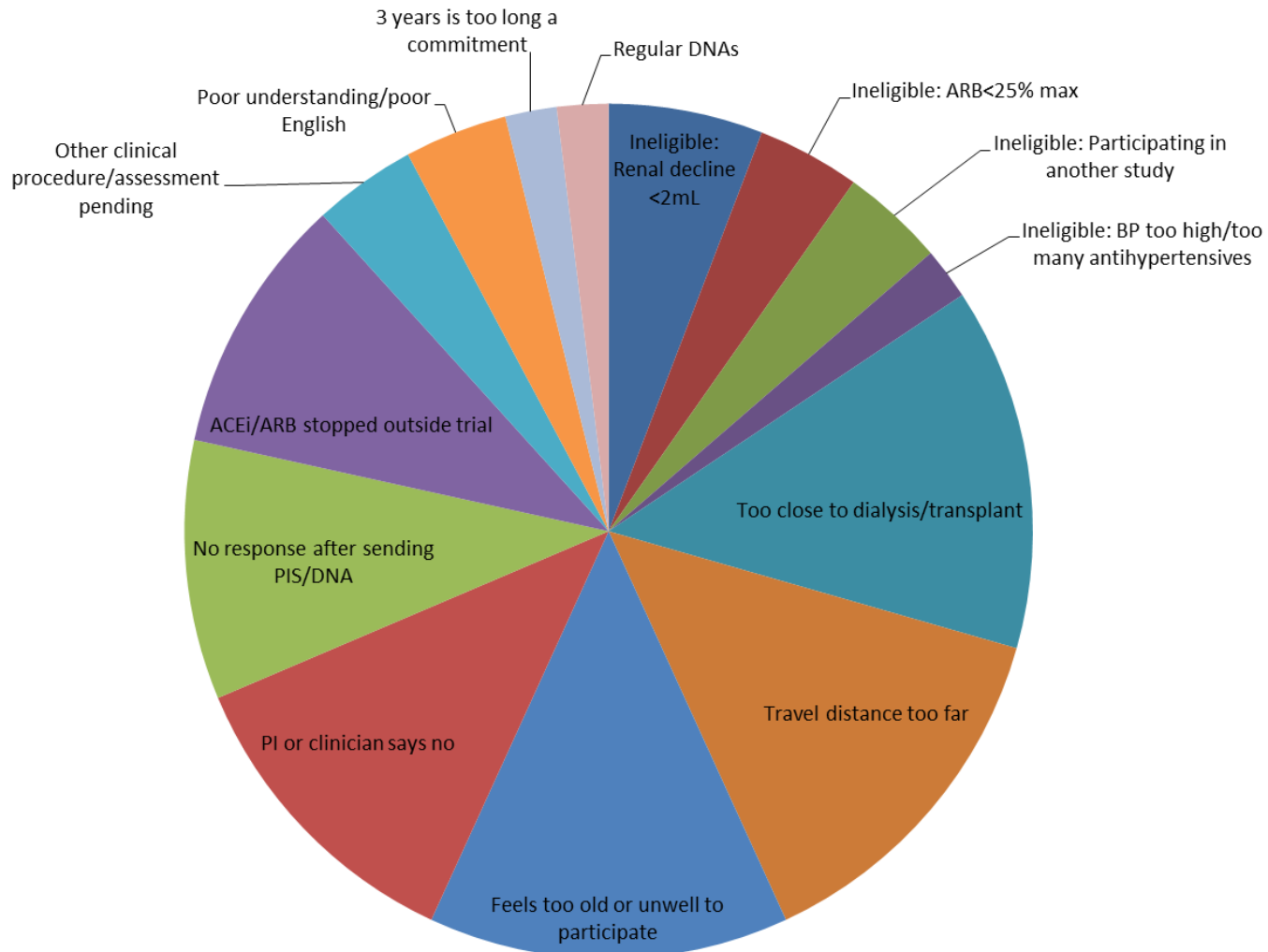
Imperial College Healthcare NHS Trust

Imperial College Healthcare **NHS**
NHS Trust

Imperial College Healthcare NHS Trust
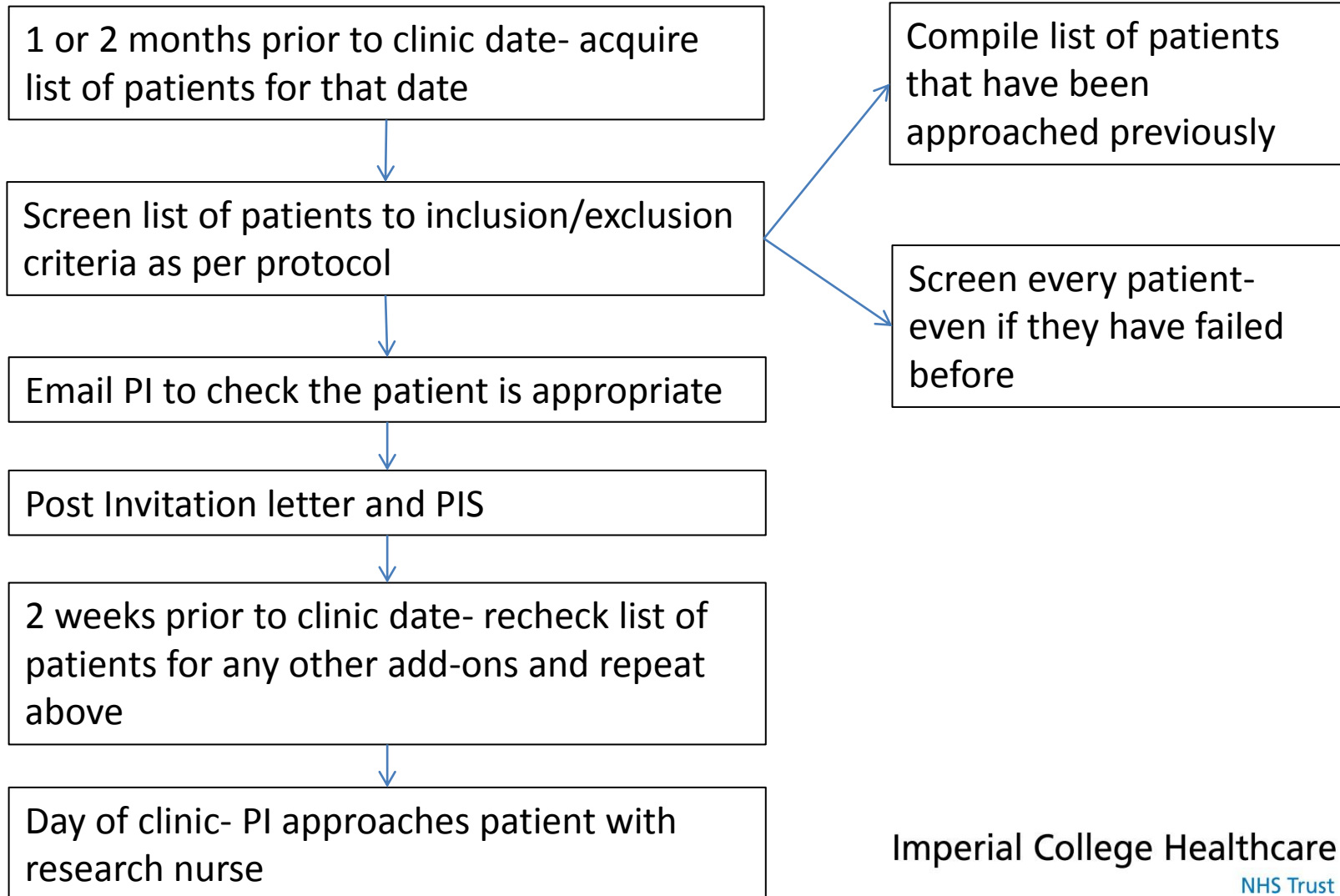
- Current recruitment count- 18

- Local target- 20

- Activation date- 26th May 2015

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Imperial College Healthcare NHS Trust Our Process

1 or 2 months prior to clinic date- acquire list of patients for that date

↓

Screen list of patients to inclusion/exclusion criteria as per protocol

↗ Compile list of patients that have been approached previously

↘ Screen every patient- even if they have failed before

↓

Email PI to check the patient is appropriate

↓

Post Invitation letter and PIS

↓

2 weeks prior to clinic date- recheck list of patients for any other add-ons and repeat above

↓

Day of clinic- PI approaches patient with research nurse

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Our screen log

STOP-ACEi : Screening Log (CONFIDENTIAL!)   ACTIVATION DATE: 26th May 2015

Trial ID	Surname	First name	Hospital no.	Date of birth	eGFR ml/min/year	Eligible – initial?	Ethnicity	Invite Letter sent?	Clinic Date	Comments
2535					-10.76	Yes	Asian	26/11/2015	03/12/2015	Recruited
					-3.16	Yes	Asian			No English. Trial requires good communication with patients for patient safety- would be unable to use an interpreter over the phone
					-4	Yes	Caucasian	04/12/2015	17/12/2015	Pt did not attend last appointment
2642					-4.03	Yes	Caucasian	01/06/2015	07/01/2016	Recruited
2923					-13.73	Yes	Black	12/04/2016		Recruited
					-3.78	Yes	Caucasian			Debbie- pt is not appropriate
					-6.06	Yes	Asian	08/01/2016	14/01/2016	BP too high in clinic
					-8.54	No	Caucasian			BP slightly high but eligible if this is better controlled; uncontrolled hypertension
2733					-18.32	Yes	Caucasian	20/01/2016	11/02/2016	Recruited
					-3.57	Yes	Caucasian	26/01/2016		Pt did not attend appointment ?unreliable
					-12.69	Yes	Asian			Debbie: patient often DNAs, unreliable
					-6.53	Yes	Asian			Patient declined
2824					-15.26	Yes	Caucasian	01/03/2016		Recruited
					-2.92	Yes	Caucasian			No longer eligible- taking part in a different interventional trial
					-5.33	Yes	Asian	08/01/2016	14/04/2016	BP too high on the day
					-5.06	Yes	Caucasian	12/04/2016		hyperkalaemic, ramipril stopped since screening
2972					-7.23	Yes	Caucasian	12/04/2016		Recruited
2998					-3.72	Yes	Caucasian	17/05/2016		Recruited
3004					-5.63	Yes	Asian	18/05/2016		Recruited
3012					-3.57	Yes	Black	18/05/2016		Recruited
					-12.83	Yes	Black			Pt not suitable because going through a hard time at the moment
					-4.81	Yes	White	16/06/2016		Recent TIA shortly before clinic visit
					-6.38	Yes	Asian	24/06/2016		Declined
					-5.33	Yes	Asian	08/01/2016		ARB self discontinued- misunderstanding at previous clinic appointment
					-2.36	Yes	Black	02/08/2016		
					-19.04	Yes	White	02/08/2016		
					-8.91	Yes	Asian	02/08/2016		
					-8	Yes	White	02/08/2016		
					-3.29	Yes	Asian			Poor English
					-4.22	Yes	White	02/08/2016		

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Hull Royal Infirmary Recruitment

Hull Royal Infirmary Recruitment

- Direct consultant referral

- Database search

- Inclusion / Exclusion lists in clinic

- Email plea

Hull Royal Infirmary Recruitment

- Electronic screening log

  - Colour coded
  - Name
  - DOB
  - NHS No
  - ACE/ARB
  - Date screened
  - Eligibility
  - Consent or refusal date
  - Comments

Hull Royal Infirmary Recruitment

- Basic eligibility search

- eGRF graph

- Any patients ambiguous liaise with PI

- Contact or 'save for later'