Focussing on Recruitment
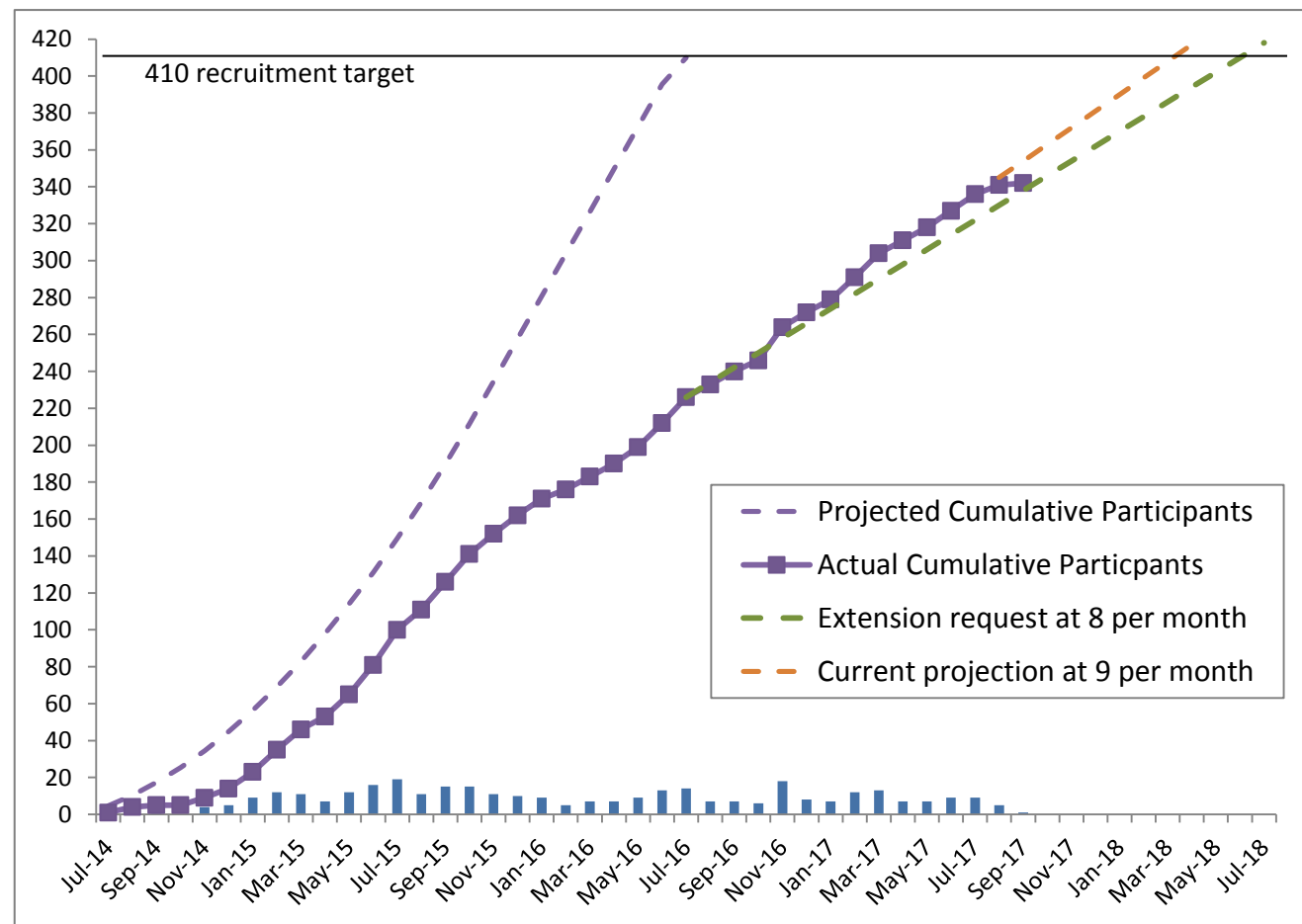
Investigator Meeting
12 September 2017 – Sheffield

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

Revised target in requested extension: 8 patients per month = 24 more months

Actual overall rate: 9 patients per month across 37 sites = end in April 2018 = 21 more months

Chart:
- 420 / 400 / 380 / 360 / 340 / 320 / 300 / 280 / 260 / 240 / 220 / 200 / 180 / 160 / 140 / 120 / 100 / 80 / 60 / 40 / 20 / 0
- 410 recruitment target
- Legend:
  - Projected Cumulative Participants
  - Actual Cumulative Particpants
  - Extension request at 8 per month
  - Current projection at 9 per month
- X-axis: Jul-14, Sep-14, Nov-14, Jan-15, Mar-15, May-15, Jul-15, Sep-15, Nov-15, Jan-16, Mar-16, May-16, Jul-16, Sep-16, Nov-16, Jan-17, Mar-17, May-17, Jul-17, Sep-17, Nov-17, Jan-18, Mar-18, May-18, Jul-18
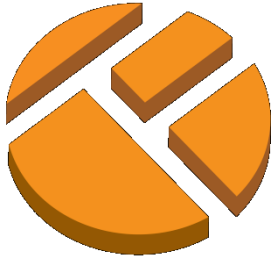
68 more to go

We're not alone!

- Review of 114 multicentre trials funded by MRC and

  NIHR HTA Programmes

  - 31% achieved the original target

  - 53% had to be extended
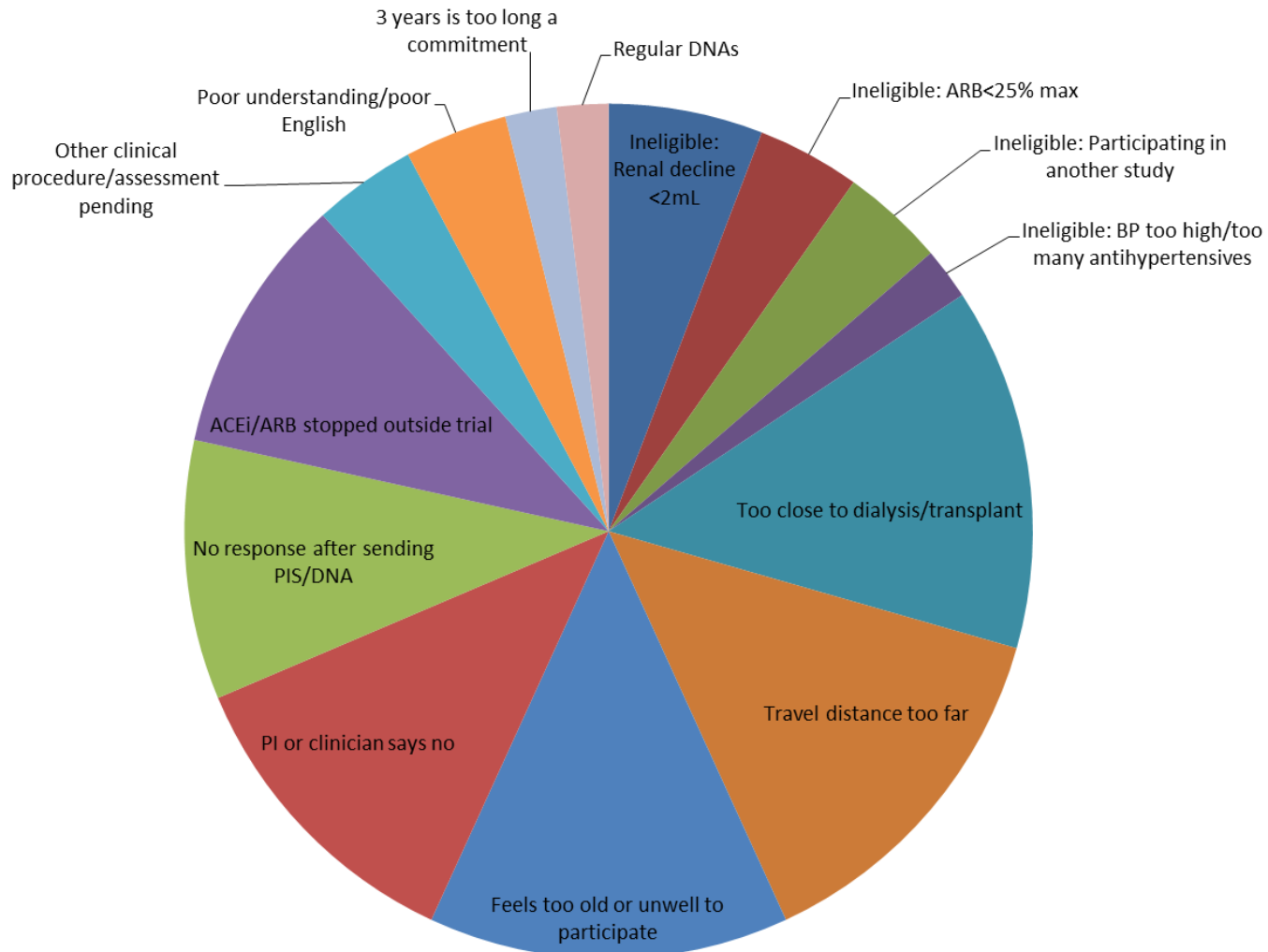
The solution?

"Recruitment for science is
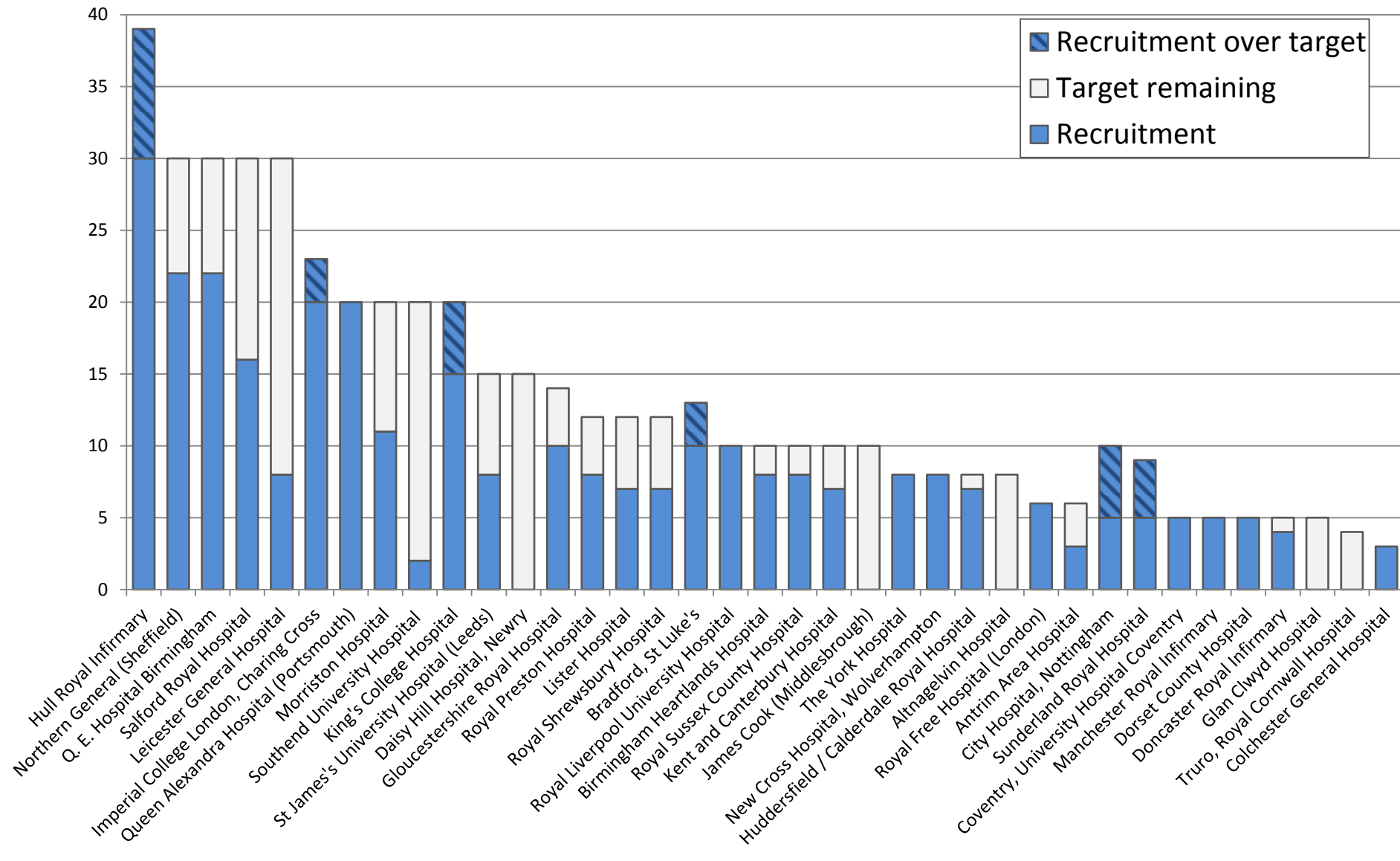
not underpinned by a science

of recruitment"

Recruitment – obstacles

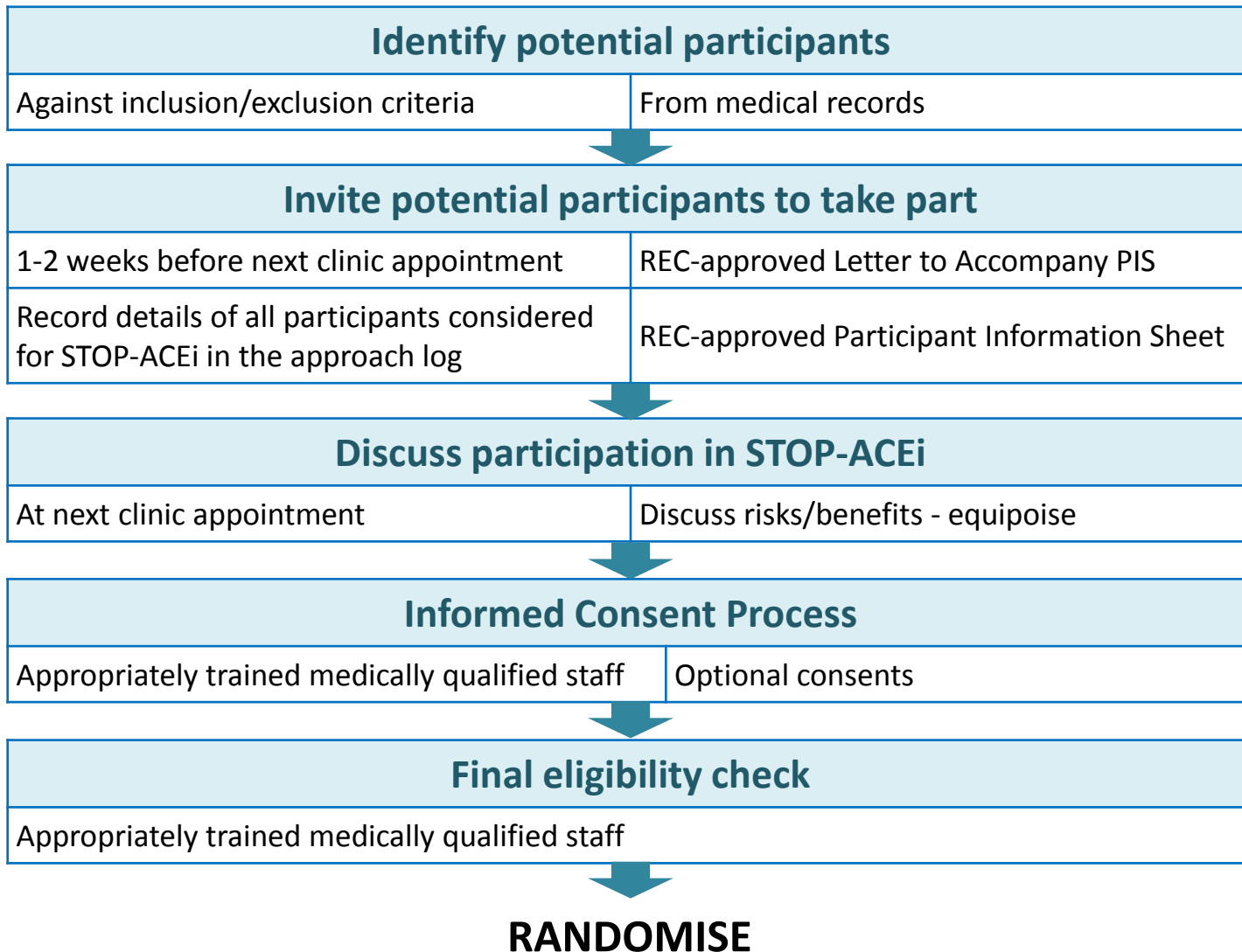**Chart showing reasons for non-participation where given**

- 3 years is too long a commitment
- Regular DNAs
- Poor understanding/poor English
- Other clinical procedure/assessment pending
- Ineligible: Renal decline <2mL
- Ineligible: ARB<25% max
- Ineligible: Participating in another study
- Ineligible: BP too high/too many antihypertensives
- ACEi/ARB stopped outside trial
- Too close to dialysis/transplant
- No response after sending PIS/DNA
- PI or clinician says no
- Feels too old or unwell to participate
- Travel distance too far

Recruitment – success rates

Patient identification

Identify potential participants	
Against inclusion/exclusion criteria	From medical records

Invite potential participants to take part	
1-2 weeks before next clinic appointment	REC-approved Letter to Accompany PIS
Record details of all participants considered for STOP-ACEi in the approach log	REC-approved Participant Information Sheet

Discuss participation in STOP-ACEi	
At next clinic appointment	Discuss risks/benefits - equipoise

Informed Consent Process	
Appropriately trained medically qualified staff	Optional consents

Final eligibility check
Appropriately trained medically qualified staff

RANDOMISE
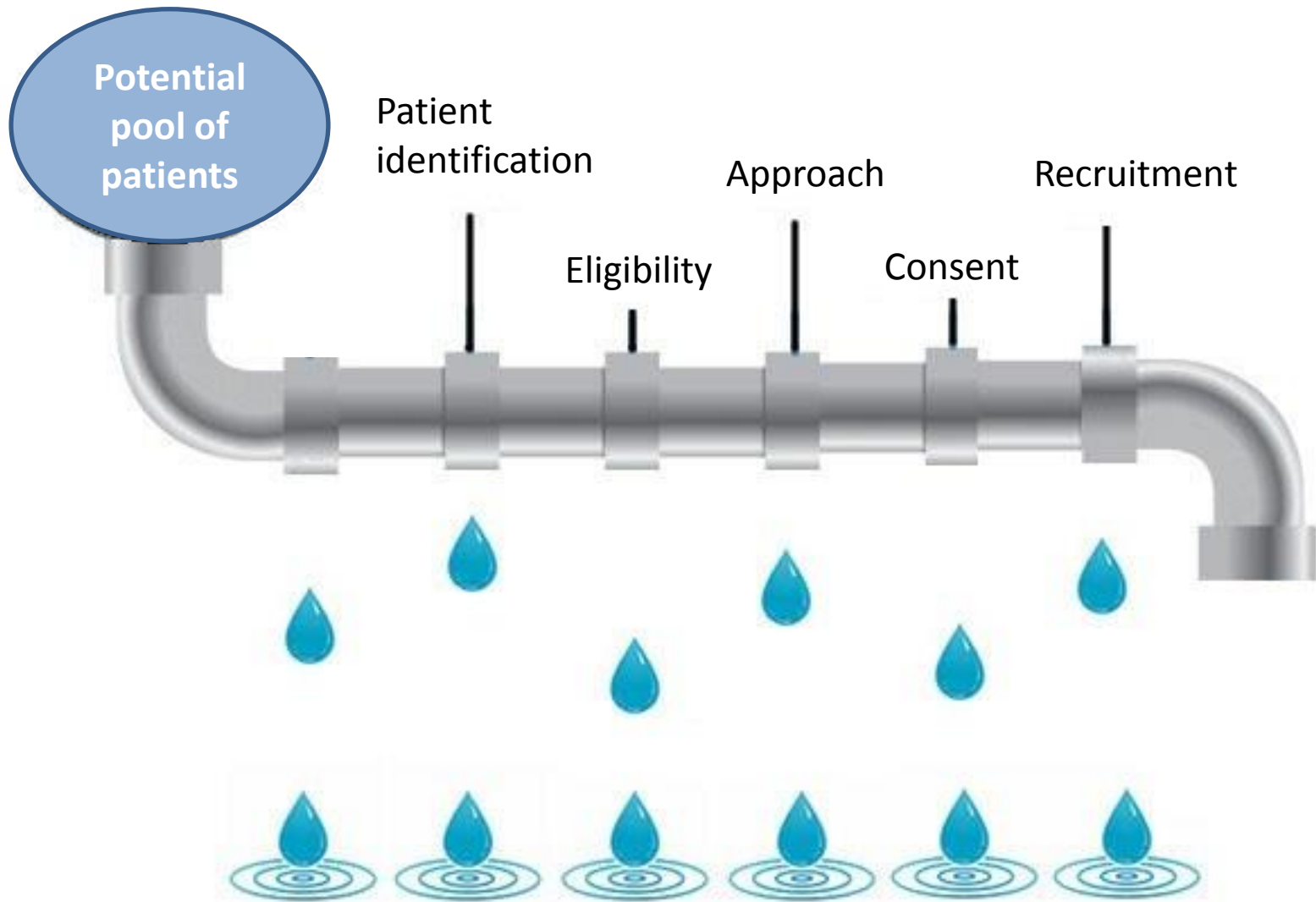
Patient recruitment

Patient identification – site approaches

- Direct consultant referral

- Database search

- Screening ahead of a clinic

- Inclusion / Exclusion lists in clinic

- E-mail plea to the department

- Fixed regular meeting between PI and RN

- New referrals

- Junior clinical staff

Patient identification – keeping track

- For the ISF:

  - Patient approach log

  - Patient screening log

- Also consider:

  - Keeping track of patients confirmed to be ineligible

  - 'Saved for later'

  - Chase for response

  - Can save the eGFR calculator

Patient approach

- Re-assurance

- Present the trial as a treatment option

- Explain the need for the trial

  - Equipoise

  - Essential to avoid conveying bias

- Probe a patient's treatment preferences and challenge misunderstandings