

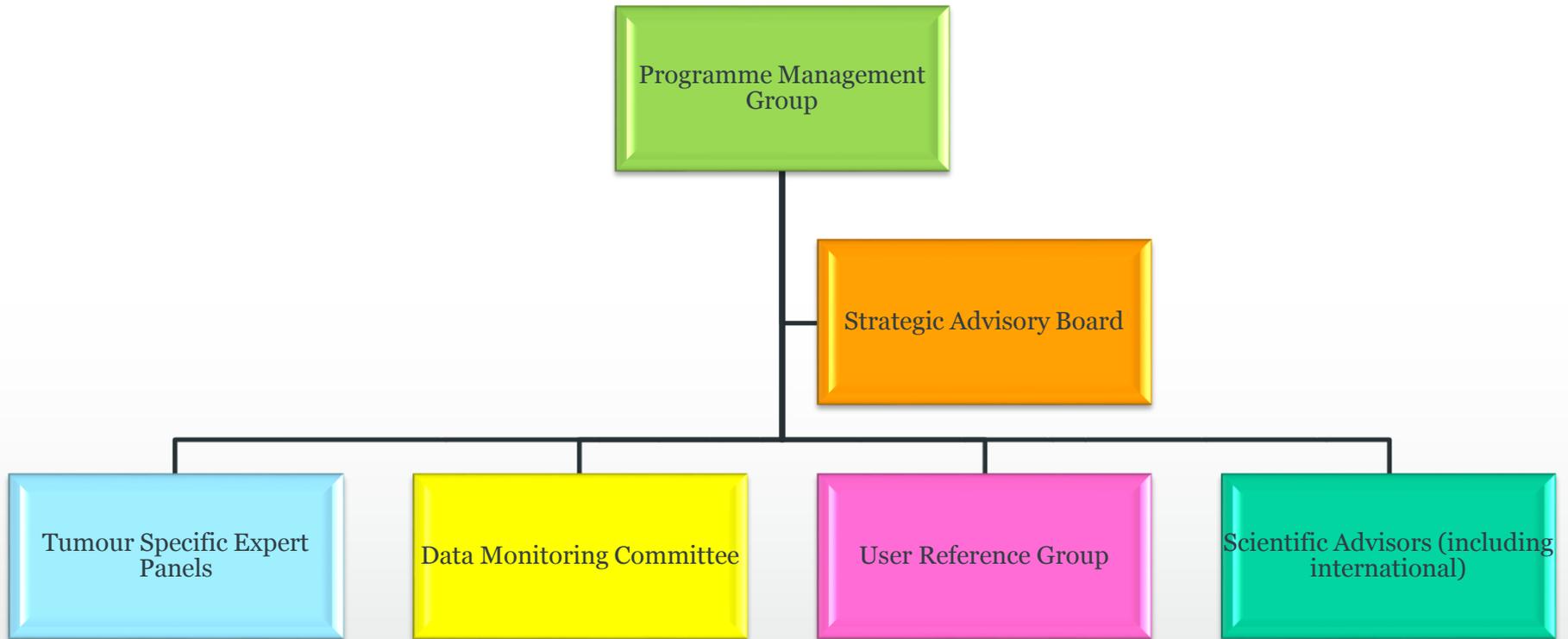
# HORIZONS

UNIVERSITY OF  
Southampton

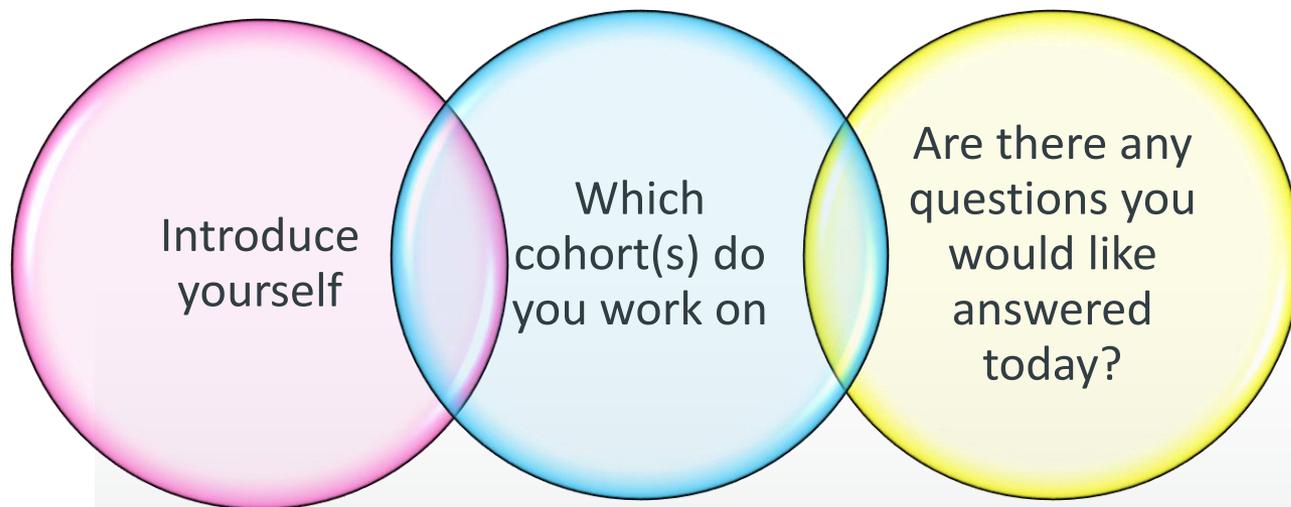
HORIZONS: a cohort study to explore  
recovery of health and well-being in  
adults diagnosed with cancer

Welcome

Macmillan Survivorship Research Group  
Faculty of Health Sciences  
University of Southampton



## Your team



## Introduction

The aim of HORIZONS is to understand how cancer and its treatment impacts on peoples lives.

It will adopt a longitudinal cohort approach.

Data will be collected from:

Patient Report  
Outcome  
Measures  
(PROMs)

Case Report  
Forms (CRFs)

Nested  
Qualitative  
Work

## Introduction

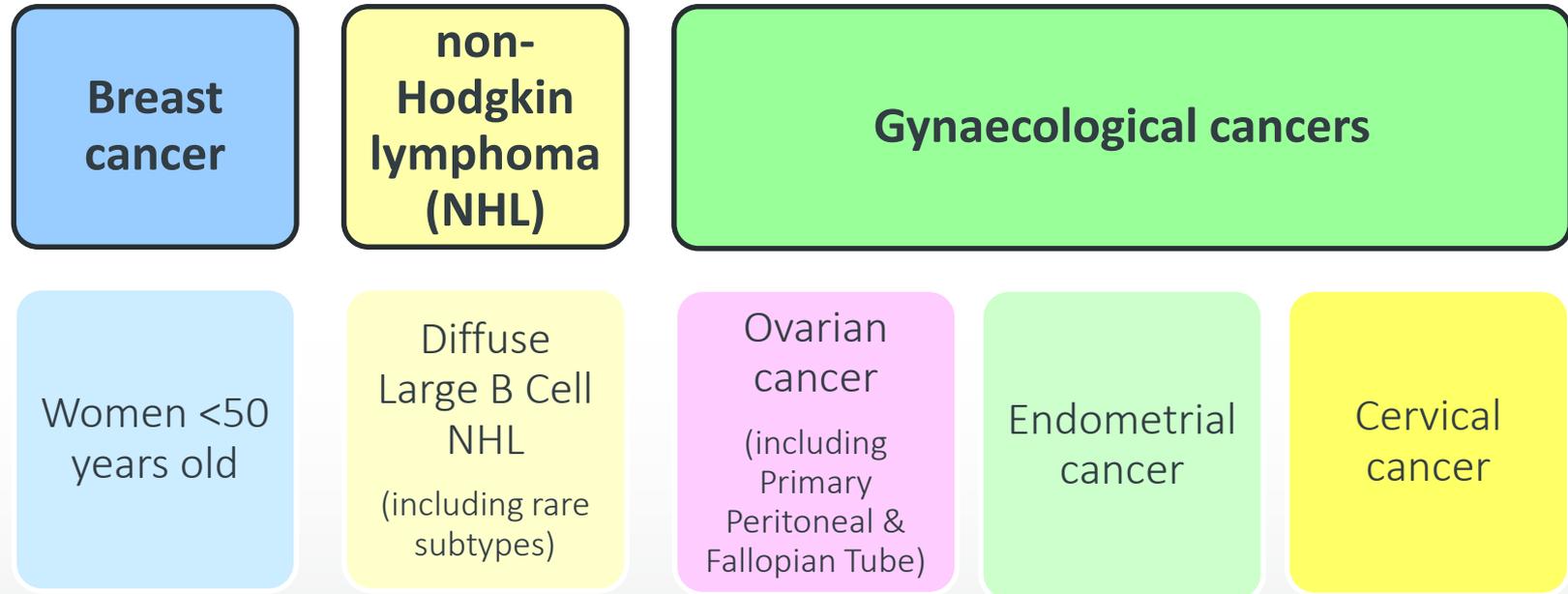
### Our research questions

- What impact does cancer and its treatment have on people diagnosed with cancer in the short, medium and long term?
- What are the health outcomes, experiences and self-management activities over the life-course across different cancer types and what influences these?
- How do people connect with and mobilise resources which enable them to self-manage consequences of cancer and its treatment?

## HORIZONS Cohort Study

- 3 years of recruitment (from Autumn 2016)
- Aim to recruit over 3,000 patients
- 6 pilot sites (Phase 1)
- Phase 2 sites opened early 2017
- Your sites represent “Phase 3” and all will be open by the end of 2017
- Over 50 sites in total

## Our initial cohorts

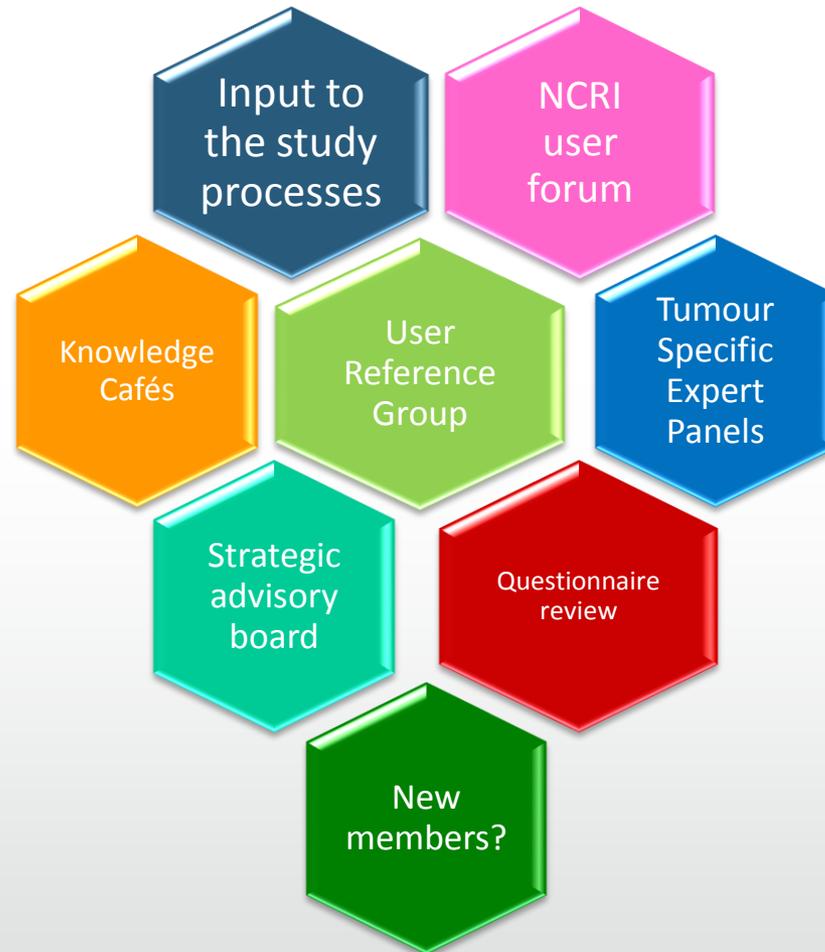


- Total sample – all eligible patients on screening log and approached
- Ideally patients will be approached before the start of primary treatment but there are some exceptions

## Other studies

- Participation in other research studies is not an exclusion criterion for this study.
- Site staff should give information to all eligible participants to allow them to choose if they want to participate in the study.
- If the patient is participating in, or considering participation in another study, HORIZONS should still be offered to the patient, unless it is an exclusion criteria of another study to which the participant is already consented.

## Importance of patients in HORIZONS study design



## Regulatory authority progress

### REC

- Favourable opinion from proportionate review June 2016
- 16/NW/0425

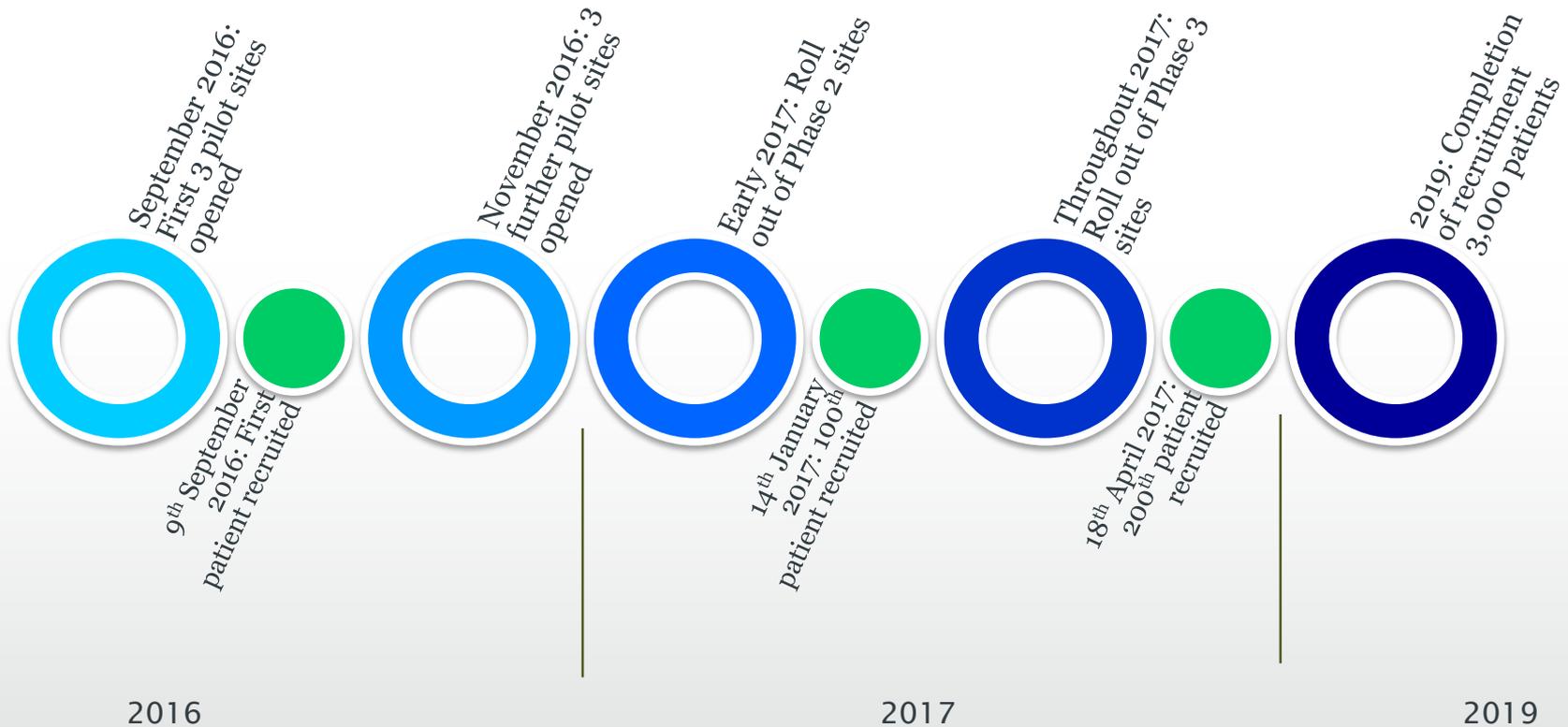
### HRA

- HRA approval January 2017 for Phase 3 sites (all of you!)
- IRAS 202342

### Portfolio

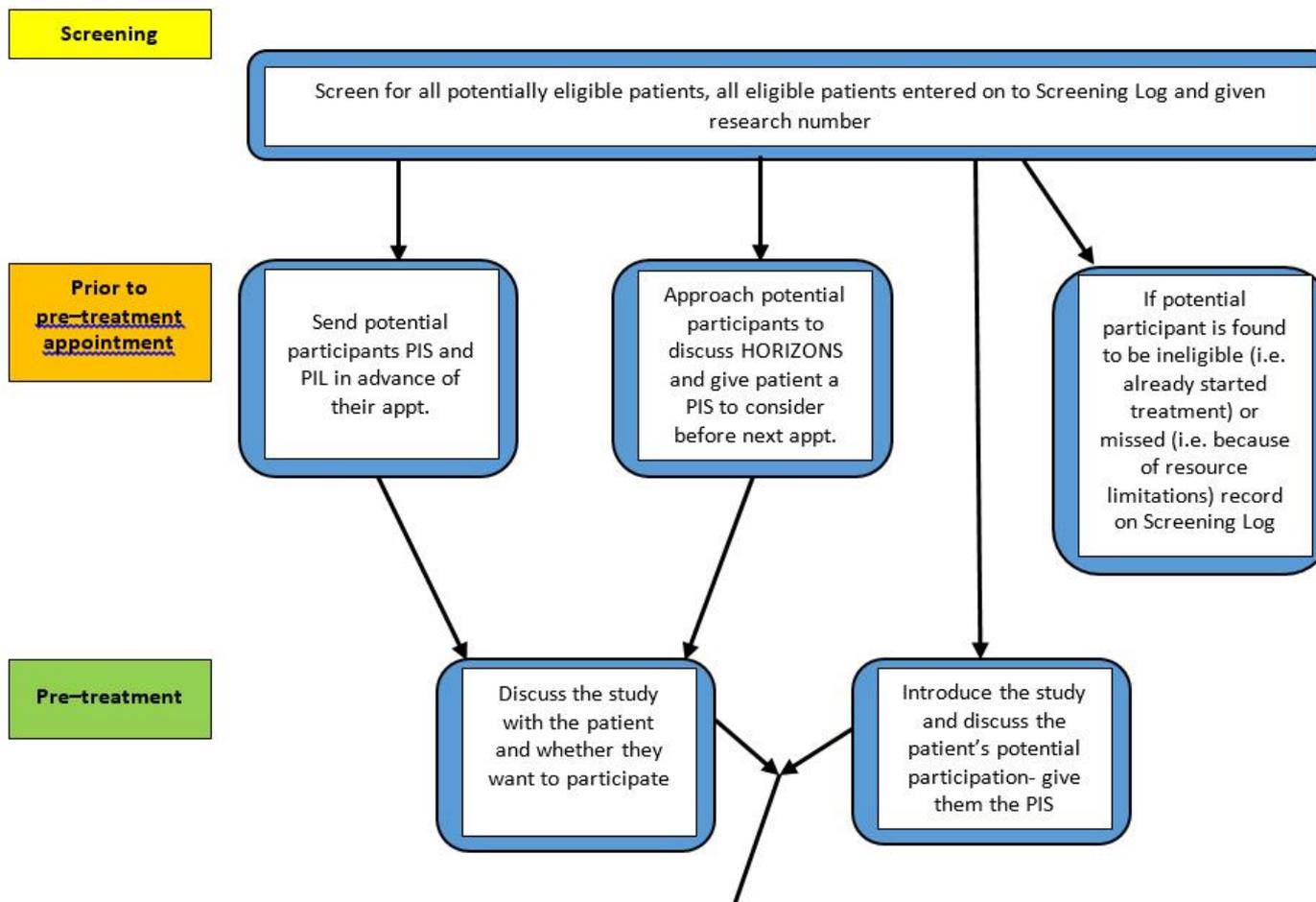
- Adopted August 2016
- Portfolio CPMS ID 31610

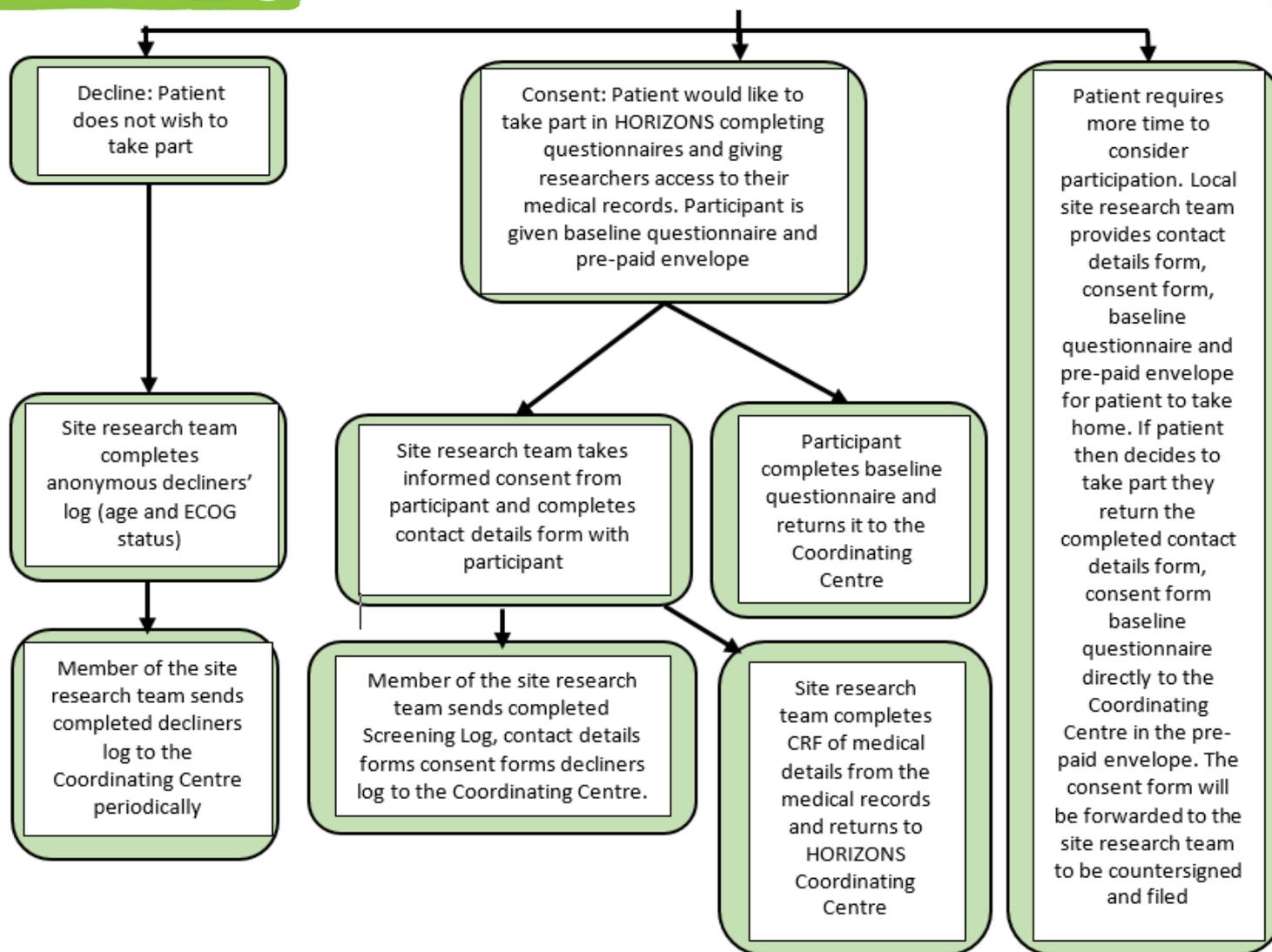
## Recruitment Timeline & Milestones



# HORIZONS

## Recruitment





## HORIZONS - **Breast Cancer Cohort** – Screening Log

Study short title	HORIZONS study: Understanding the impact of cancer diagnosis and treatment on everyday life	Ethics No.	16/NW/0425
Sponsor	University Hospital Southampton NHS Foundation Trust	Principal Investigator	
Site		Chief Investigator	Prof. Claire Foster
Site ID		Agreed day for faxing	

FAX COMPLETED LOG SHEET TO HORIZONS – WEEKLY: 023 8059 7967 or 7951

Log Sheet No:

NHS & Hospital Number <i>CONCEAL prior to faxing</i>	Screening Date <i>dd/mm/yy</i>	Study ID; Pt initials, site ID, cohort=B, Consecutive study number <i>BS01B001, LC01B002 etc</i>	Outcome:	1. Full Consent / 2. Reduced Consent/ 4. Documents taken home: Study ID include initials eg: BS01B001 <sup>#</sup>		Proposed treatment start date 1. Full consent/ 2. Reduced consent/ 4. Documents taken home		
				3. Declined / 5. Missed Approach/ 6. Ineligible following screening: XX instead of initials eg: XX01B001 <sup>#</sup>				
			Full consent <sup>#</sup>	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___		
			Reduced consent only <sup>#Y</sup>	2.	Fax Reduced Consent Form and completed Reduced Demographic form <sup>#</sup>	Proposed Tx start ___/___/___		
			Declined any participation <sup>Y</sup>	3.	Reason declined and fax completed Declined Demographic form:			
			Documents taken home <sup>#</sup>	4.		Proposed Tx start ___/___/___		
			Missed approaching (eligible)	5.	Reason not approached:			
			Ineligible following screening <sup>5</sup>	6.	Reason ineligible following screening:			
			Full consent <sup>#</sup>	1.	Fax Contact Details Form and Consent Form	Proposed Tx start ___/___/___		
			Reduced consent only <sup>#Y</sup>	2.	Fax Reduced Consent Form and completed Reduced Demographic form <sup>#</sup>	Proposed Tx start ___/___/___		
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			Declined any participation <sup>Y</sup>	3.	Reason declined and fax completed Declined Demographic form:			
			Documents taken home <sup>#</sup>	4.		Proposed Tx start ___/___/___		
			Missed approaching (eligible)	5.	Reason not approached:			
			Ineligible following screening <sup>5</sup>	6.	Reason ineligible following screening:			

<sup>#</sup> Add Study ID to Questionnaire or Demographic form / <sup>Y</sup> Complete basic demographics, with patient's permission  
<sup>5</sup> Minimum criteria for screening; diagnosis of primary breast cancer, clinical stages I – III and awaiting primary treatment with curative intent

## Full sample cohort- Reviewing activity

Total eligible screened

Approach those eligible

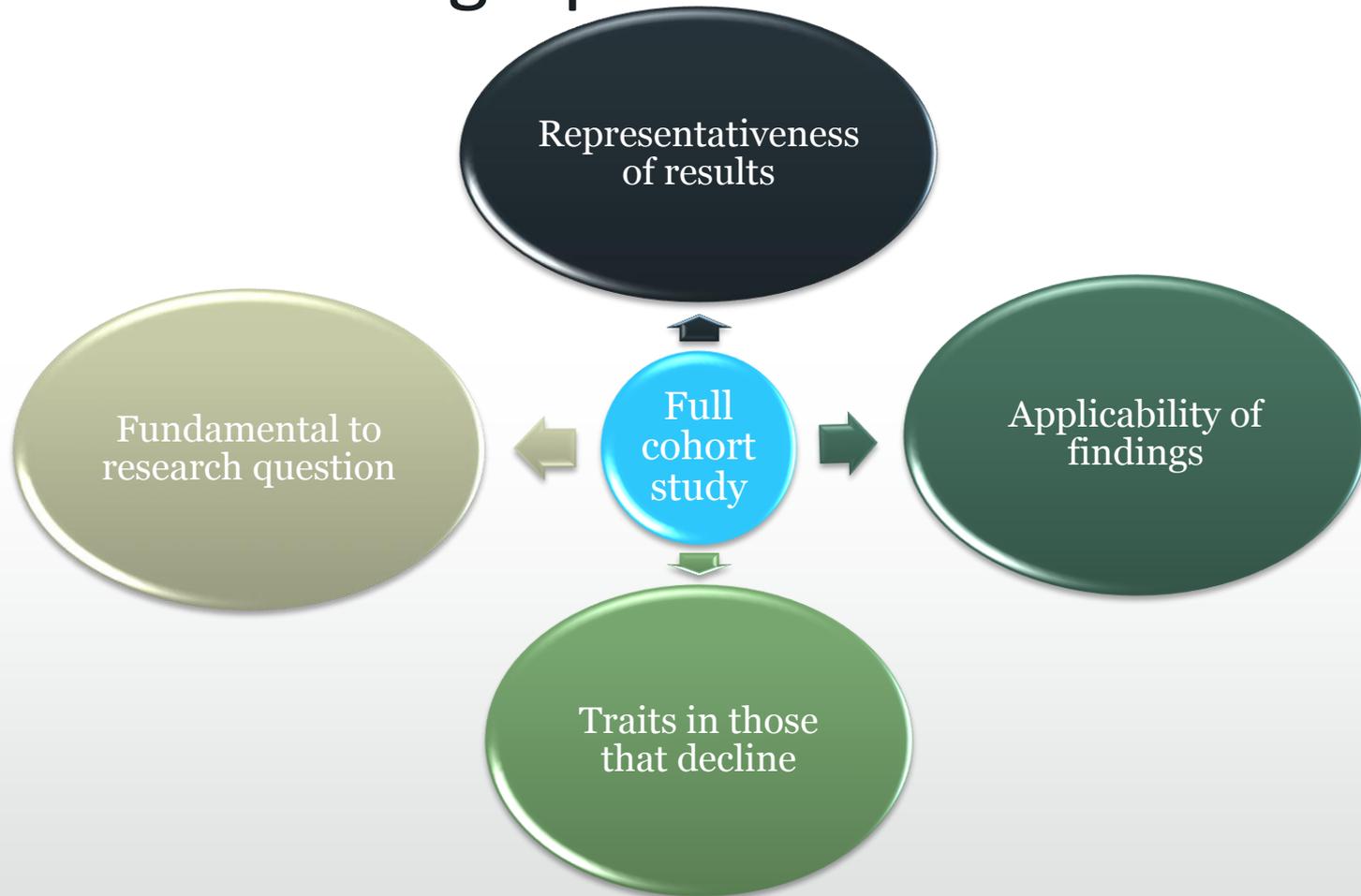
Approached consented

## Introduce study to patients

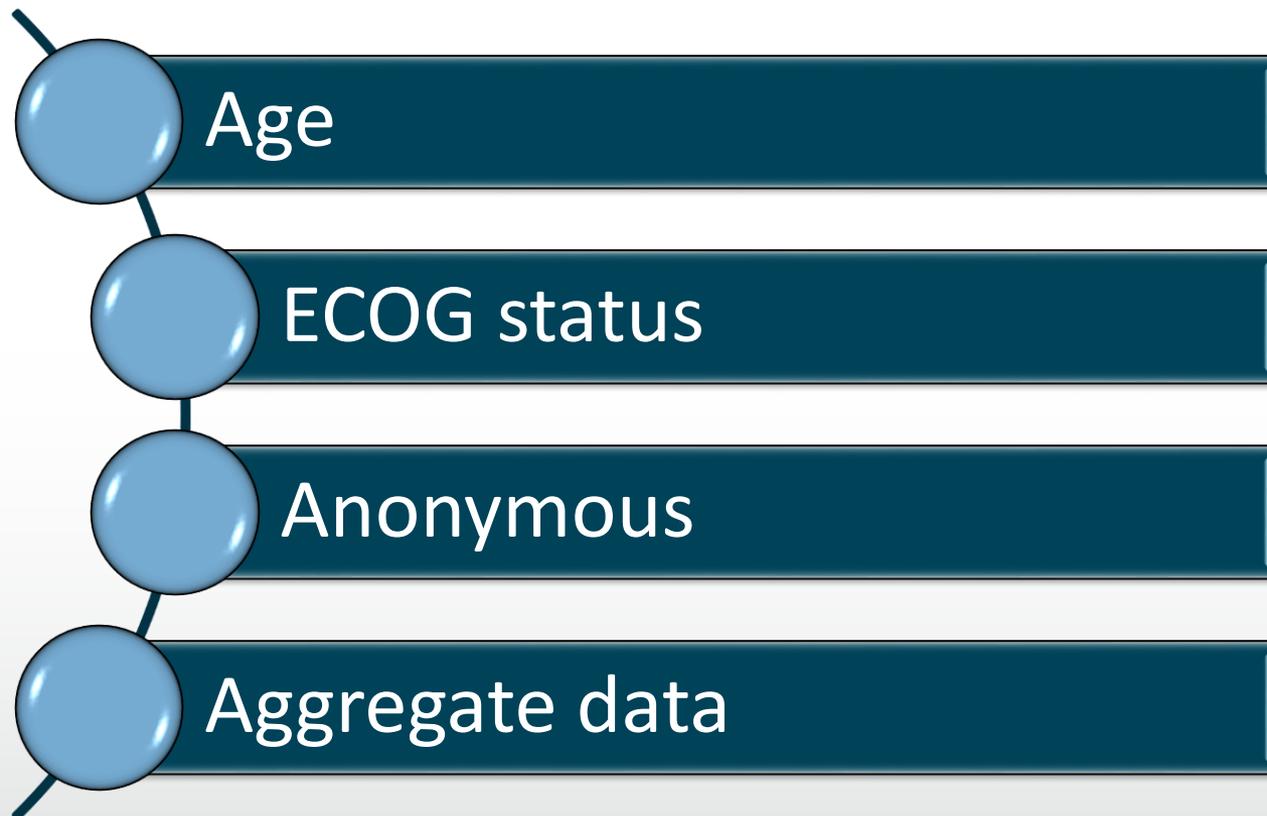
**Participant Pack** – review with participant & discuss study (HORIZONS Coordinating Centre will send out packs to sites)

- Letter of Invitation
- HORIZONS Flyer
- Patient Information Sheet
- Consent Form
- Contact Details Form
- Questionnaire
- Freepost return envelope to the HORIZONS Coordinating Centre

## Full cohort demographics



## Decliners log



## Baseline Questionnaires – before treatment

- Participant completes Baseline Questionnaire and seals it in pre-paid reply envelope
- Participant or site staff member posts pre-paid envelope containing baseline questionnaire to HORIZONS Coordinating Centre

## Follow Up Questionnaires

- New time points! Protocol version 3
  - 3m, 12m, 18m, 24m annual to 5 years
- Sent centrally by HORIZONS coordinating centre
- Paper or online

- Site resource; recorded SIV's, documents
- Participant online completion of follow-up questionnaires; 3m, 12m, 18m, 24m, annual

[www.HORIZONS-hub.org.uk](http://www.HORIZONS-hub.org.uk)

# HORIZONS

Understanding the impact of cancer diagnosis and treatment on everyday life

## Welcome to the HORIZONS Programme website

HORIZONS is a large study of people across the UK who have had a diagnosis of cancer.

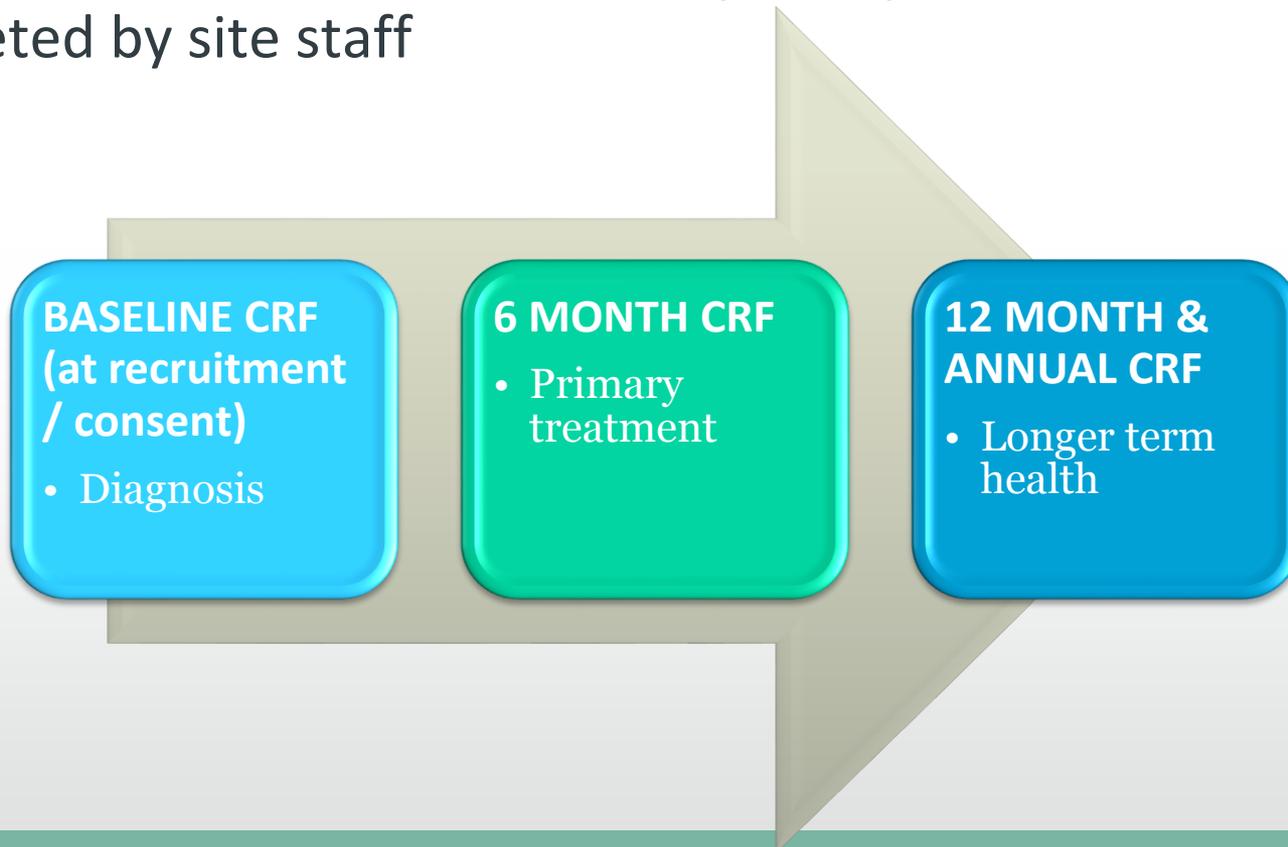
We are interested in how a diagnosis of cancer and its treatment affects a person's life over time. The aim is to understand what is important to people with cancer during their treatment and in the months and years afterwards which will help to inform support services in the future.

Please use the buttons below to navigate our site.



## Case Report Forms

- For each full and reduced consent participant, CRFs will be completed by site staff



## Pilot sites

- University Hospital Southampton NHS Foundation Trust
- Hampshire Hospitals NHS Foundation Trust (Winchester and Basingstoke)
- Norfolk and Norwich University NHS Foundation Trust
- Ipswich Hospital NHS Trust
- Surrey and Sussex Healthcare NHS Trust
- Tameside and Glossop Integrated Care NHS Foundation Trust

## Phase two sites

### Northern Ireland

- Antrim Hospital (Northern Health and Social Care Trust)

### Wales

- Betsi Cadwaladr University Health Board

### Scotland

- University Hospital Crosshouse and University Hospital Ayr (NHS Ayrshire and Arran)
- Beatson West of Scotland Cancer Centre (NHS Greater Glasgow and Clyde)
- Borders General Hospital (NHS Borders)

### England North West

- The Royal Preston Hospital (Lancashire Teaching Hospitals NHS Foundation Trust)
- Macclesfield Hospital (East Cheshire NHS Trust)

### England North East

- Queen Elizabeth Hospital (Gateshead Health NHS Foundation Trust)

- St James' Institute of Oncology (Leeds Teaching Hospitals NHS Trust)

### - England Midlands

- New Cross Hospital (The Royal Wolverhampton NHS Trust)

### - England South West

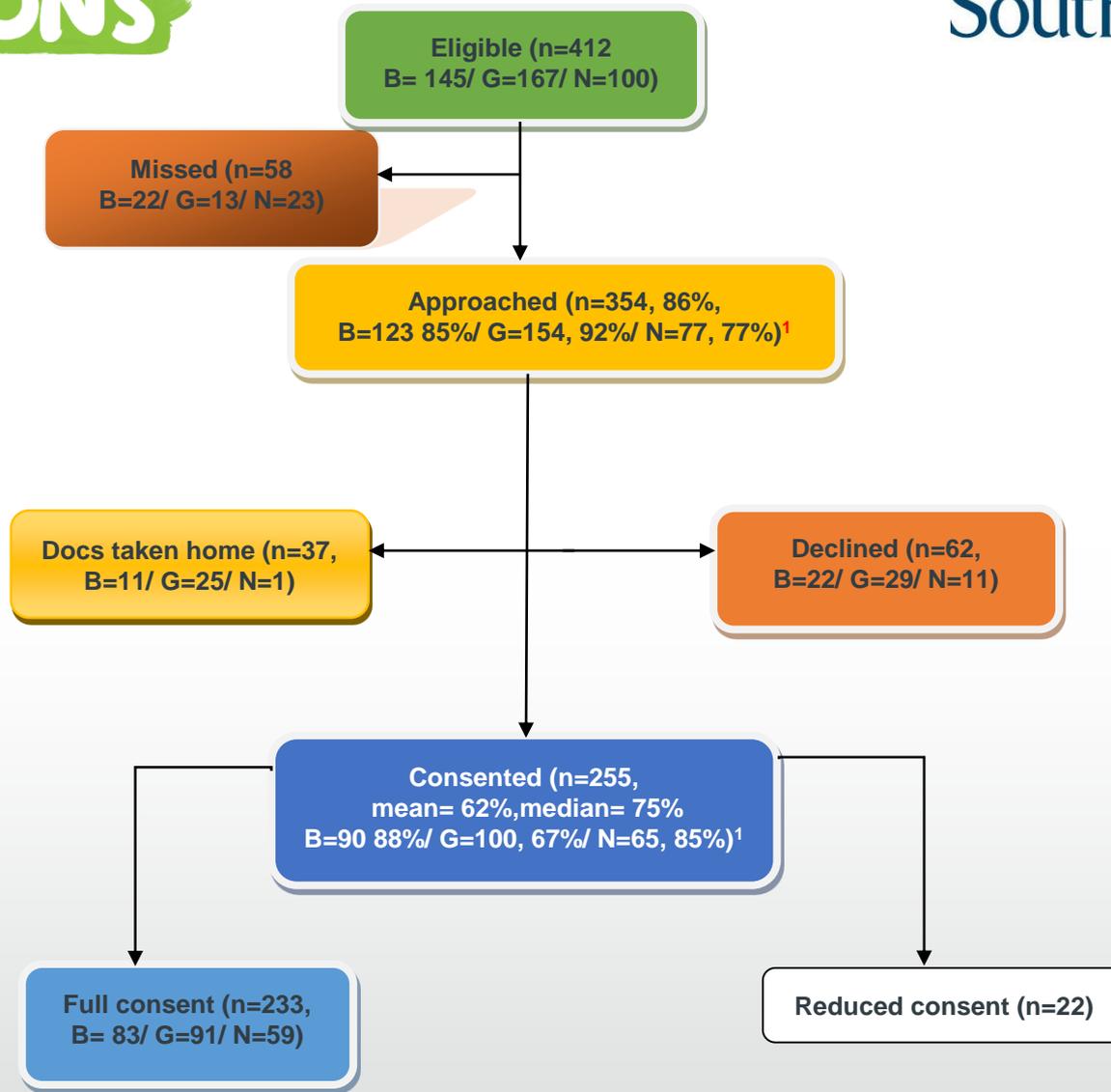
- Derriford Hospital (Plymouth Hospitals NHS Trust)

### - England South East

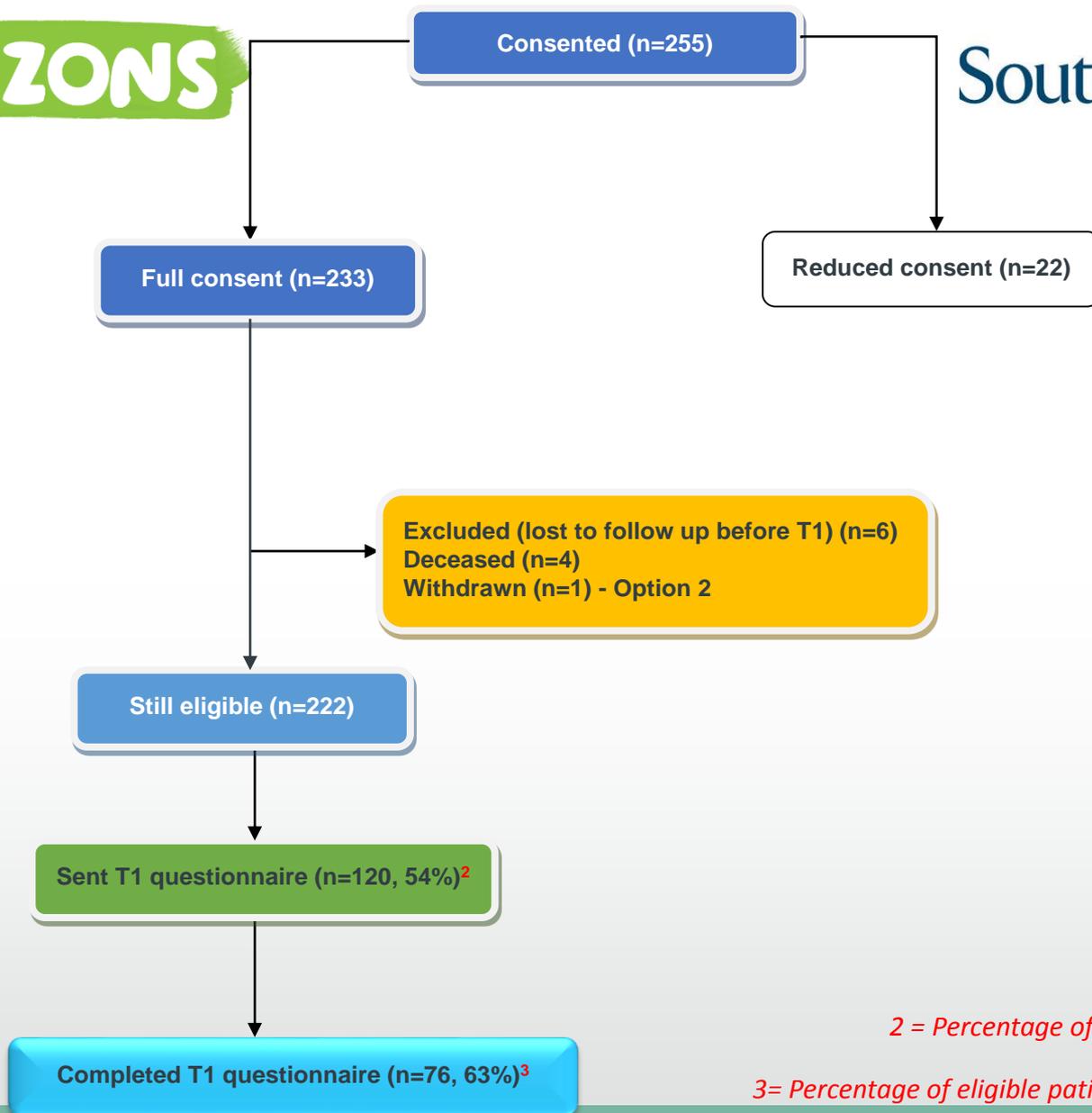
- East Kent Hospital NHS Foundation Trust

March 17	April 17	May 17	June 17	July 17
Cwm Taf	Lothian	Frimley Park	Oxford	Leighton
Hywel Dda	Dumfries	Basildon	York	Oldham
Great Yarmouth	Tayside	Derby	Sherwood Forest	Nottingham
Portsmouth	Brighton	Salford	Bradford	Manchester
	Salisbury	Huddersfield		
	Kings Lynn	Gillingham		
August 17	September 17	October 17	November 17	December 17
Newcastle	Dartford	St. Albans	Maidstone	Mount Vernon
West Bromwich	Weston-Super-Mare	Blackburn	Bedford	Central Manchester
Royal Stoke	Bath	Carlisle	Guildford	
N. Tyneside	Dudley	East Sussex	Lincoln	
Bristol		Wirral	Worcestershire	





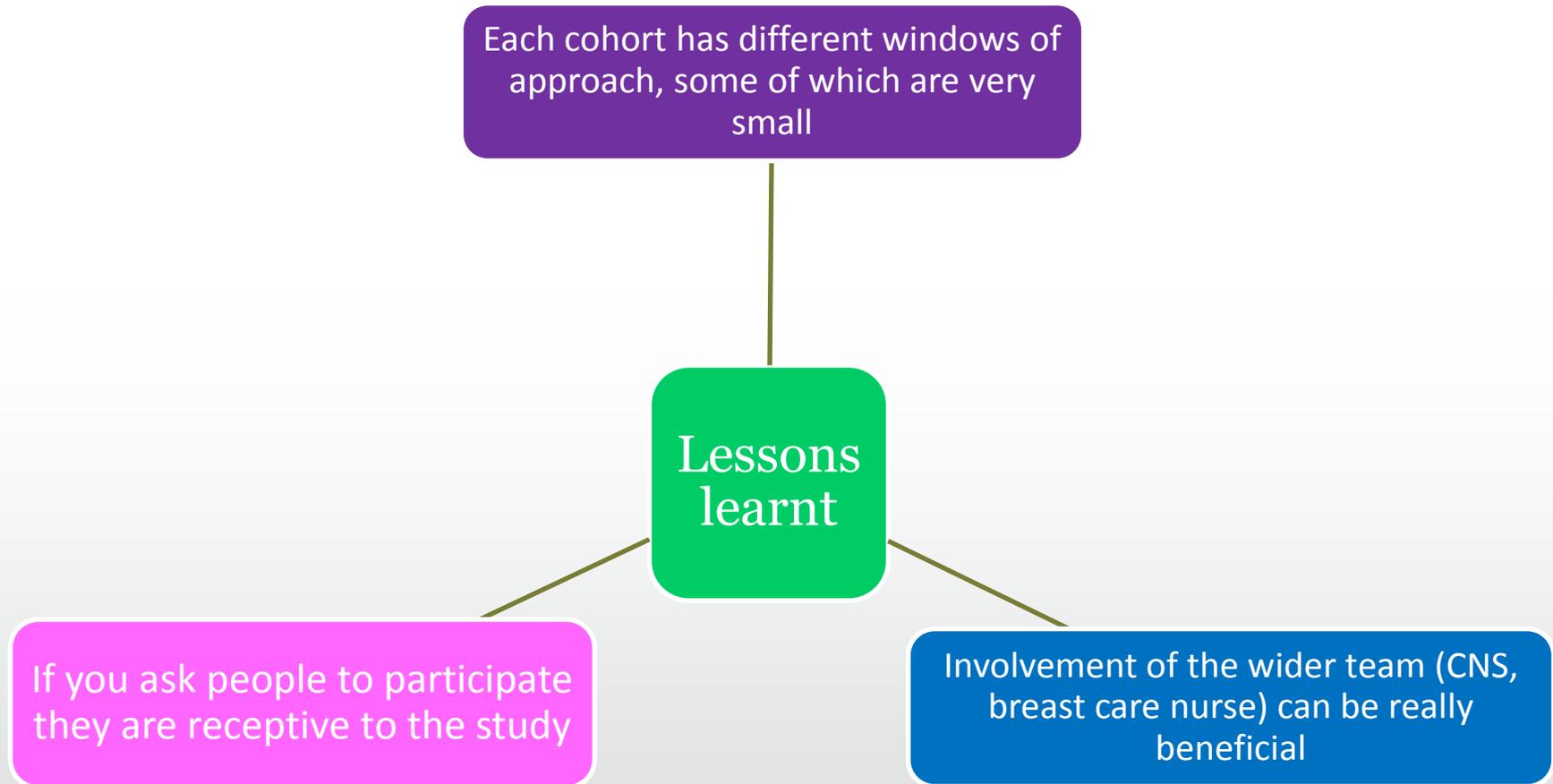
<sup>1</sup> = Percentage of eligible patients



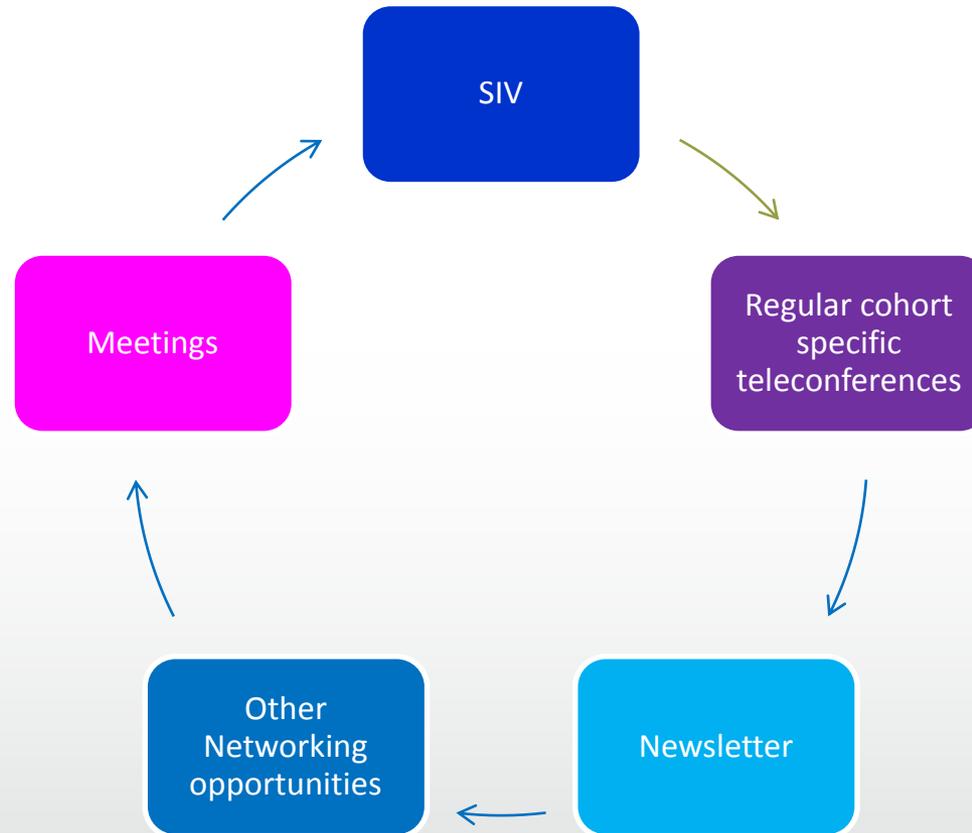
*2 = Percentage of eligible patients*

*3 = Percentage of eligible patients sent a T1 questionnaire*

## What have we learnt so far?



## Keeping in touch





Prof Claire Foster  
Chief Investigator



Dr Lynn Calman  
Senior Research Fellow



Dr Becky Foster  
Research Fellow  
Eligibility and CRF queries



Dr Josh Turner  
Research Fellow  
Eligibility and questionnaire queries



Faye Doyle  
Programme Manager  
Strategic advice



Becci Petch  
Trial Coordinator  
Study Set up and day to day queries



Amber Cole  
Senior Trial Administrator  
Day to day queries, 2 week status  
update checks



Bjoern Schukowsky  
Trial Administrator  
Screening logs, status updates CRF  
reminders

[HORIZONS@soton.ac.uk](mailto:HORIZONS@soton.ac.uk)

## Any questions

