

building a caring future

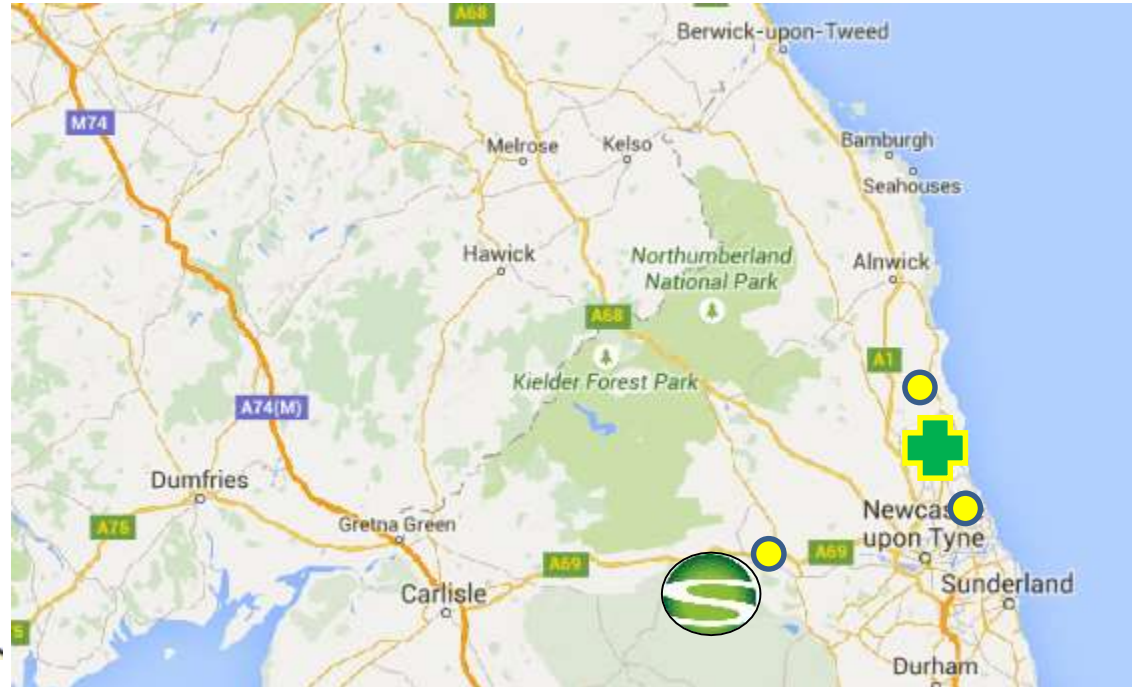
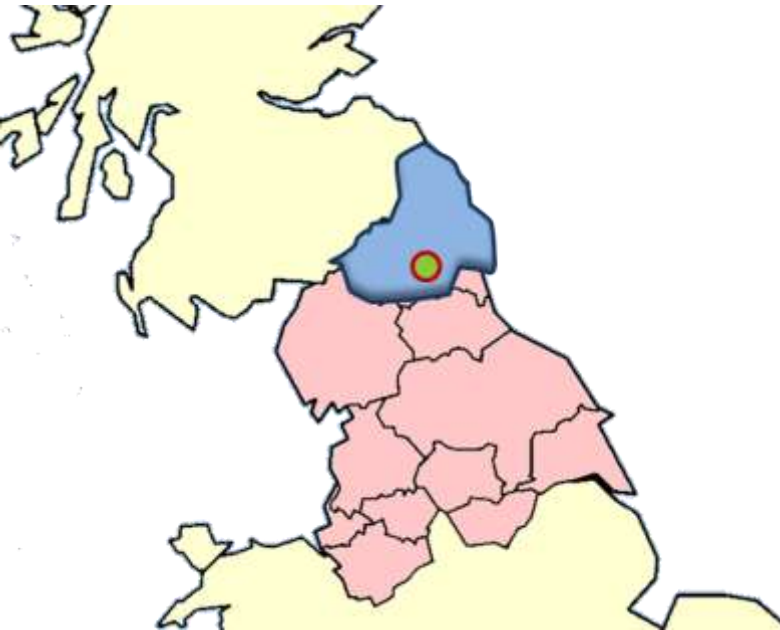
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The first of its kind, a partnership to deliver clinical trials –
Northumbria Healthcare NHS Foundation Trust and
Synexus Ltd

Miss Caroline Potts & Dr Chris Price

Background

- Northumbria Healthcare NHS Foundation Trust
 - Hospital and Community Health Services in North Tyneside
 - Hospital, Community Health Services & Adult Social Care services in Northumberland
 - 500,000 patients and 9,500 staff
 - Research active: NIHR CRN, industry and sponsor
- Synexus Ltd
 - A global Site Management Organisation (SMO)
 - 28 dedicated research sites across 9 countries
 - Hexham General Hospital hosts the 8th UK Synexus dedicated research centre (DRC)
 - Customers include the top 18 pharmaceutical companies in the world – AMGEN, AstraZeneca, Merck, Lilly, Pfizer, Roche, Novartis ..
- Initial approach made to the Trust in March 2012



The theory

- Increase capacity
 - Access to more targeted patient groups
 - Trust geography
- Increase capability
 - Access to clinical expertise
 - Access to hospital facilities
- Increase business opportunities
 - Studies that neither party could perform alone
 - Synexus global contacts + NHS platform

Early discussions

- What were we trying to do in the short and medium term
- Would we be in line with NIHR CRN objectives, or in competition
- Would any potential partnership limit opportunities for R&D growth
- Relationships with PI, support staff and GPs
- Would clinical support services want extra volume
- Where would the new site be located
- Why hadn't anyone else done this

The big build

- Contract agreed for an initial five year period
- Six months of renovation
- Governance structures required
 - Study level
 - Indemnity for personnel working on site
 - Data protection
- What studies would run through the new Centre
- Getting to understand how each other work
- Defining success



Go for launch July 2014

THE JOURNAL WEDNESDAY, JULY 30, 2014

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NEWS

New clinical trials unit opens doors

Helen Roe
Health Reporter
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A NEW medical research centre has opened at a North East hospital to increase the number of clinical trials carried out in the region.

Private company Synexus and Northumbria Healthcare NHS Foundation Trust have joined forces to set up the research centre at Hexham General Hospital in Northumberland.

The partnership will focus on clinical trials and is the first of its kind between a private company and the NHS. It is hoped that the collaboration will benefit patients in the area.

Prof Richard Walker, clinical director of research and development at Northumbria Healthcare NHS Founda-

tion Trust, said: "At Northumbria we believe everyone should be able to take part in appropriate clinical trials if they would like to.

"This partnership will bring a wider variety of trials to the North East giving more people the chance to take part.

"We're delighted to be working in partnership with Synexus. They are a very successful company with more than 20 years' experience in running research centres worldwide.

"This partnership will provide us with opportunities to work together to deliver clinical research studies relating to a variety of conditions and usually will focus on those conditions which affect large numbers of people."

Synexus runs clinical trials throughout the world working across a range of medical conditions. The



► Sarah Beebey, MD of Synexus and Northumbria Healthcare NHS Foundation Trust's Prof Richard Walker.

idea behind the firm's new approach is to increase the number of potentially complex studies being undertaken, with the support and experience of the clinical staff and services provided by the trust at the hospital.

Sarah Beebey, Synexus' UK managing director, said: "This is a very exciting partnership as it potentially signals a new way of working for the clinical trials sector that will enable UK patients to access new treatments

and will also help ensure the UK clinical trials industry remains competitive on the global stage.

"This is groundbreaking and, we hope, the start of something that will replicate across the UK so that even more people can benefit."

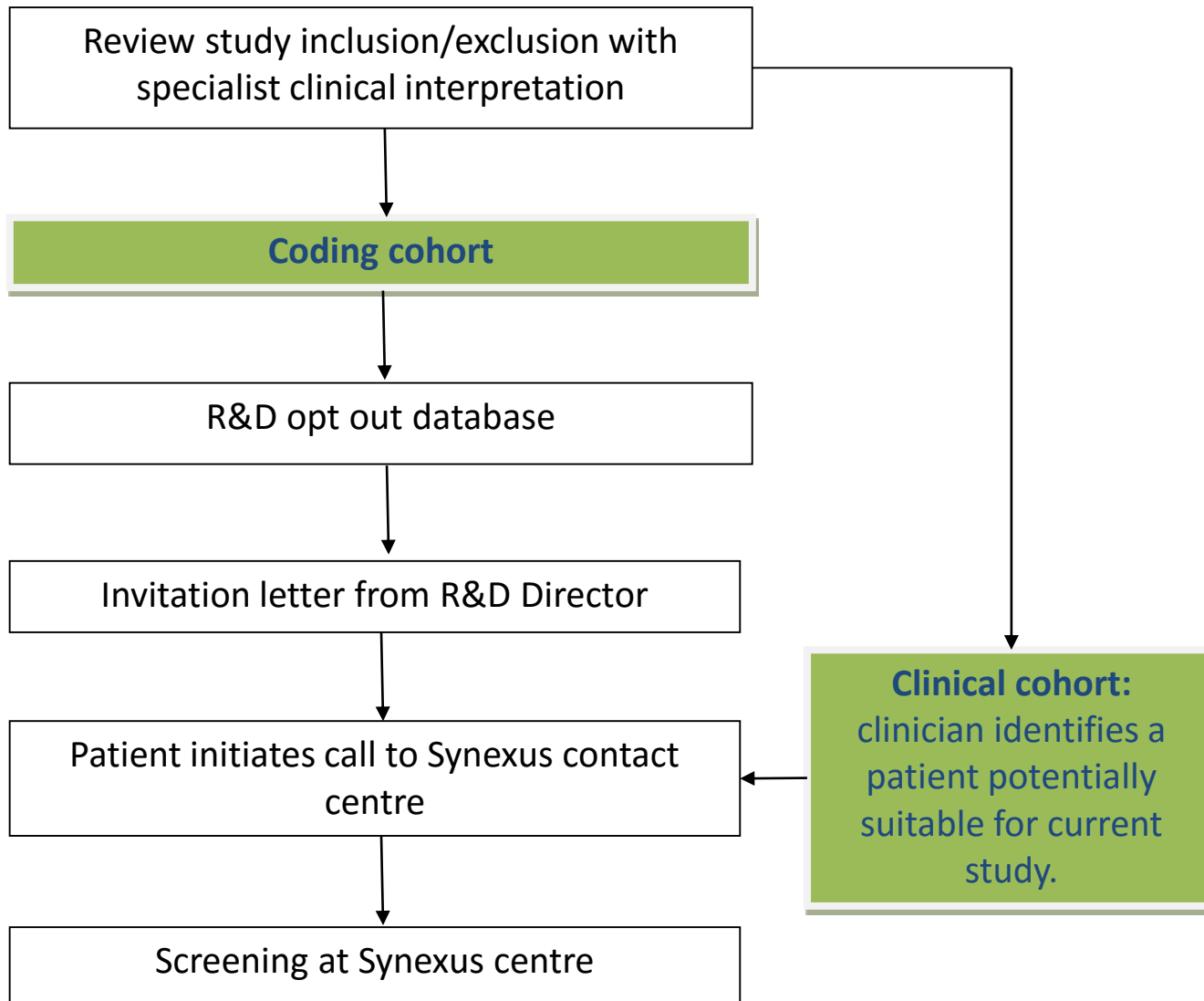
Clinical trials are carried out in order to advance medical understanding and develop more effective treatments. Synexus and Northumbria Healthcare will focus on com-

paring new treatments with the best currently available treatment or a replacement.

Synexus conducts trials across a range of conditions with particular emphasis on cardiovascular, diabetes and obesity, musculo skeletal, respiratory and central nervous system trials.

These clinical areas echo those in which Northumbria Healthcare carries out a number of research studies.

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Using existing NHS administration systems



Adobe Acrobat
Document

	Search Criteria	June Count	June All	September Clean	Total sent
Run 1	Criteria 1 Male 18-49	900			
	Criteria 2 Male 50-80	4308			
	Criteria 3 Female 18-59	1902			
	Criteria 4 Female 60-80	3155	10265		
Run 2 + diagnosis of hypercholesterolemia	Criteria 1 Male 18-49	231			
	Criteria 2 Male 50-80	2393		2337	2337
	Criteria 3 Female 18-59	567			
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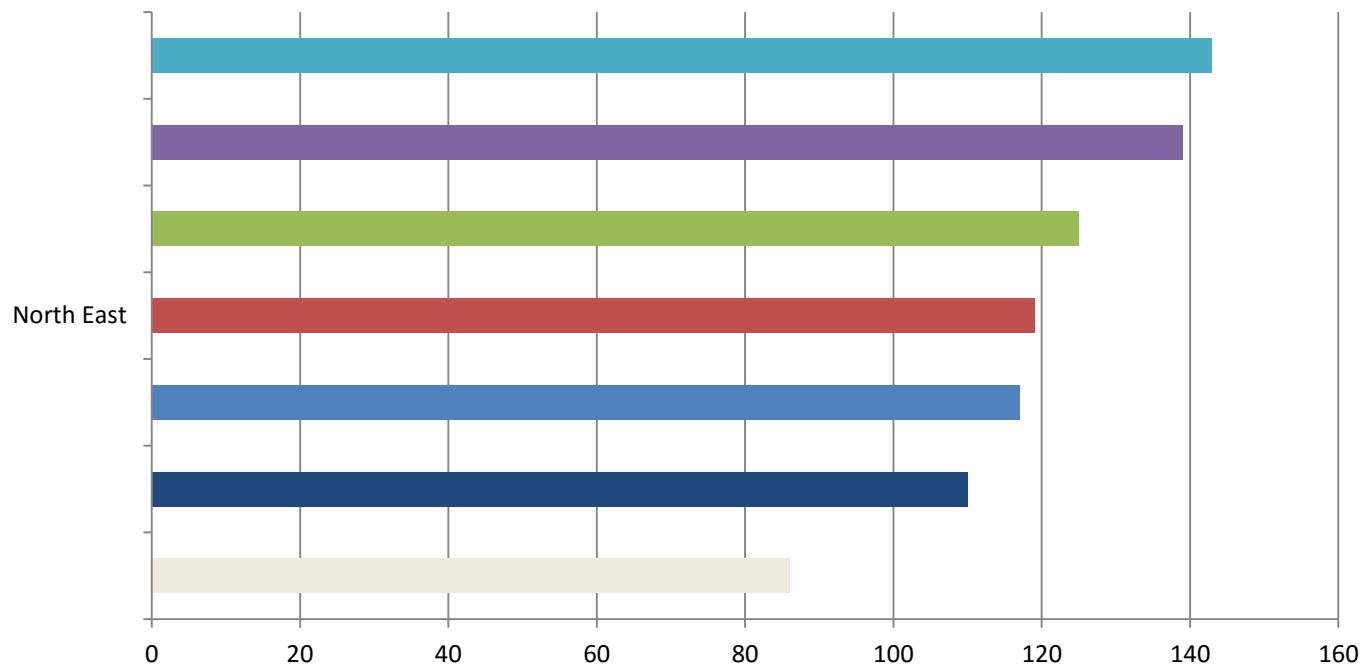
	Traditional	Partnership
Set-up	Individual local investigators	Synexus national coordination plus local clinicians
Screening	Clinical opportunities	Systematic inclusion/exclusion search of hospital database
Outreach	Clinical teams	Healthcare provider on behalf of partnership
Consent	Clinic appointment	Research centre appointment
Further information	Clinical research team	National call centre

The first 12 months

- Little overlap with studies on the portfolio
- Awareness raising with clinical teams within the Trust
- Weekly conference calls to discuss study feasibility and general business updates
- Development of new systems to identify potential study participants, whilst maintaining patient confidentiality
- CRN activity recognition

Headline results

- Approx 13 patients per month, randomised into studies



Evolution

- Data system reliability
- Synexus pipeline expanding
- CRN industry activity discussions
- Clinical service changes
- Floor space

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Thank you