WARWICK
THE UNIVERSITY OF WARWICK

USING RESEARCH TO IMPROVE PATIENT ACCESS TO NEW TECHNOLOGIES

A Health Technologies Research Programme

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Overview

- **A thriving MedTech sector in critical for the UK**, delivering cutting edge treatments and software for UK patients & the economy

- **Difficulties delivering research hamper MedTech growth**, despite a strong history of innovation in the UK

- **Orthopaedics matters:** Lower limb problems the 2nd most common reason for long term sickness (1M people)

- Typically **6-10 years** for UK patients to get access to new orthopaedic innovations

Independent report

Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report

Updated 26 May 2023

Contents

Foreword

The UK is blessed with a rich, diverse and creative academic sector with 4 of the world's 10 leading universities in the field of international research. Matched with an entrepreneurial culture that is second only to the United States, this makes our science sector the envy of the world. But in the fields of medicine and life sciences, inventions and discoveries alone do not change lives. For a therapy, device, diagnostic or digital tool to reach patients, a long, often laborious process of translating insights into products and then testing their safety and efficacy through clinical trials is required.

The UK has a magnificent track record in this area, both in our historic achievements and recent successes, such as the COVID-19 vaccine and therapeutic trials. These

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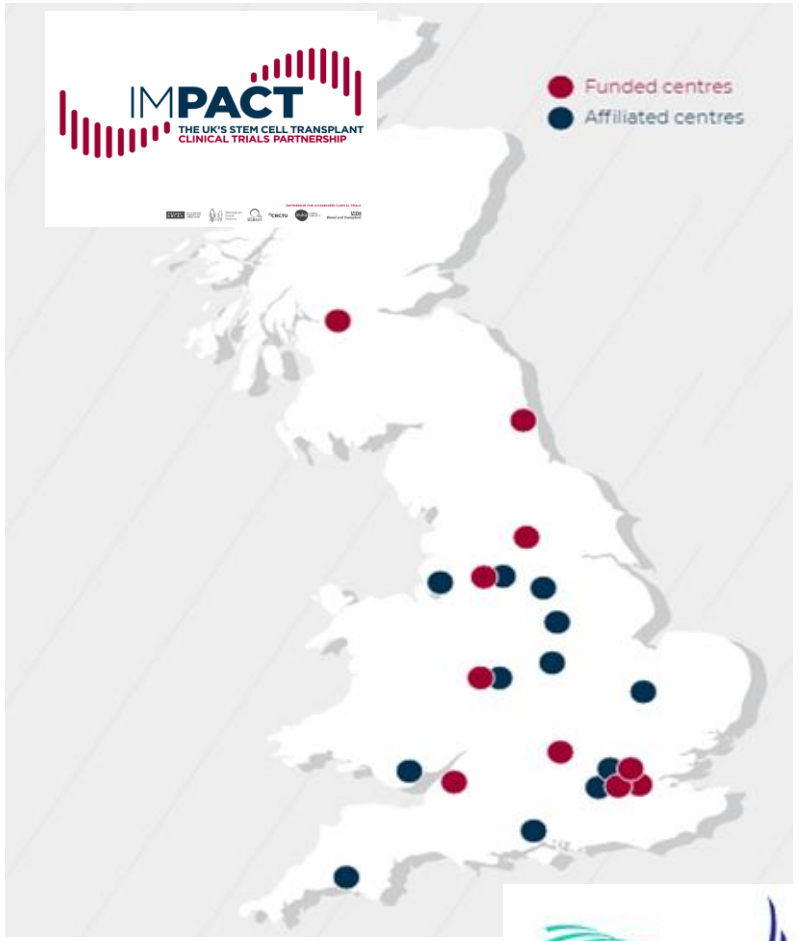
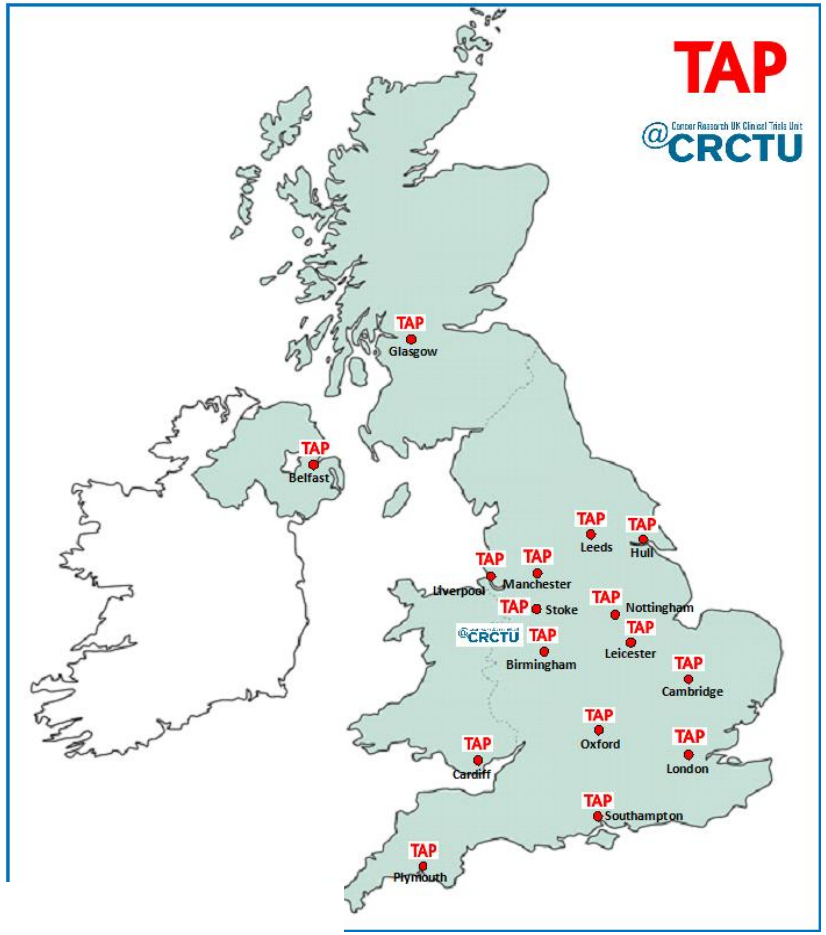
Case study: Accelerating Clinical Trials – a new blood cancer trial delivery vehicle

Blood cancers remain one of the most common malignancies and there is justified excitement that the recent development by the global biopharmaceutical sector of a wave of potentially transformative new drug and cellular therapies could transform clinical outcomes. To take advantage of this opportunity, Accelerating Clinical Trials (ACT) Ltd (a company limited by guarantee) was established in December 2021 to accelerate the delivery of high-quality trials for blood cancers by addressing barriers to trial delivery, including: insufficient trial capacity to match the sudden expansion in the number of potential new therapies; outdated delivery models; and challenges to patient recruitment including the need to utilise genomic stratification.

Funded by a £5 million pump-priming grant from the charities Cure Leukaemia and Anthony Nolan and NHS Blood and Transplant, the ACT operational hub provides new trial delivery capacity for a mixed portfolio of clinically prioritised industry sponsored and academic investigator trials. In its first 12 months, ACT attracted investment from 2 international pharmaceutical companies to deliver 2 globally significant practice-informing trials in acute myeloid leukaemia and

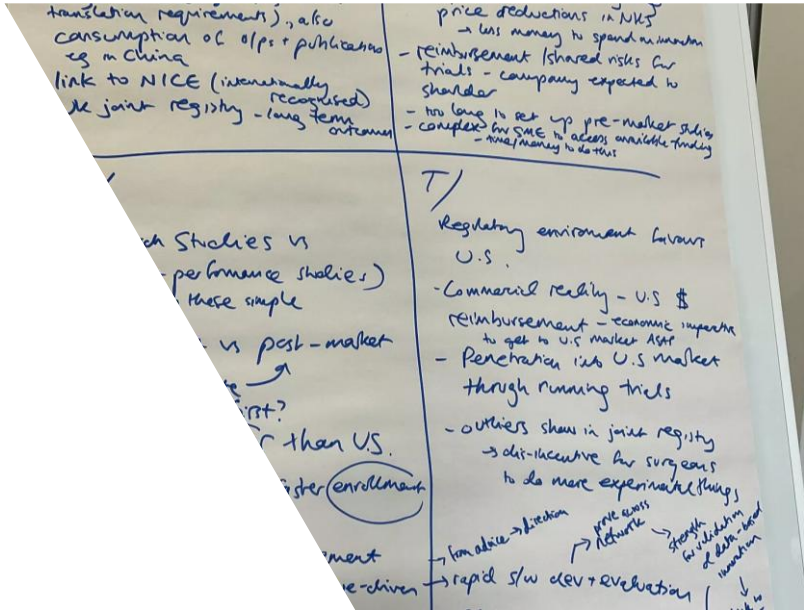
Haemato-Oncology





ACT
ACCELERATING CLINICAL TRIALS FOR PATIENTS

Orthopaedic Device Research Workshop – London, March 2024



Strengths

- ***UK highly regarded for data and research – including link to NICE***

Weaknesses

- More extensive regulatory burden & lower profit in UK/EU than the US
- Uncertainty about how to deliver pre-market studies in the UK

Opportunities

Multi-centre research opportunity to:

- ***Do pre-market (and post-market) work faster than in US (e.g. "catch up" via rapid recruitment)***
- Safety and performance studies are needed, as well as trials for more novel technologies *>>inform UK and global markets*
- Provide data relevant to NHS procurement & NICE
- Leverage rich data environment in NHS (ie ***registries***, routine data, trials networks)

Threats

- Regulatory environment favours US *(?but does it now)*

Idea: Orthopaedic research accelerator

Research Recruitment Network

- **Pre-primed recruiting network of sites with dedicated research nurses/staff & established contracts**

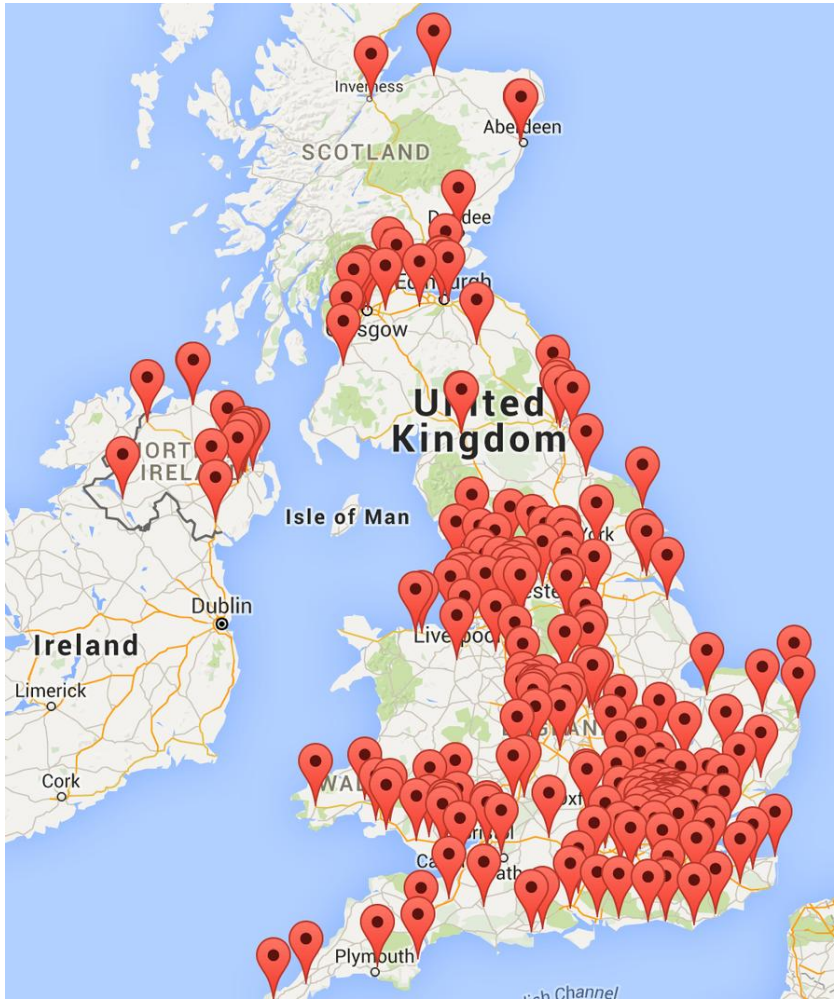
(scale = recruit quickly)

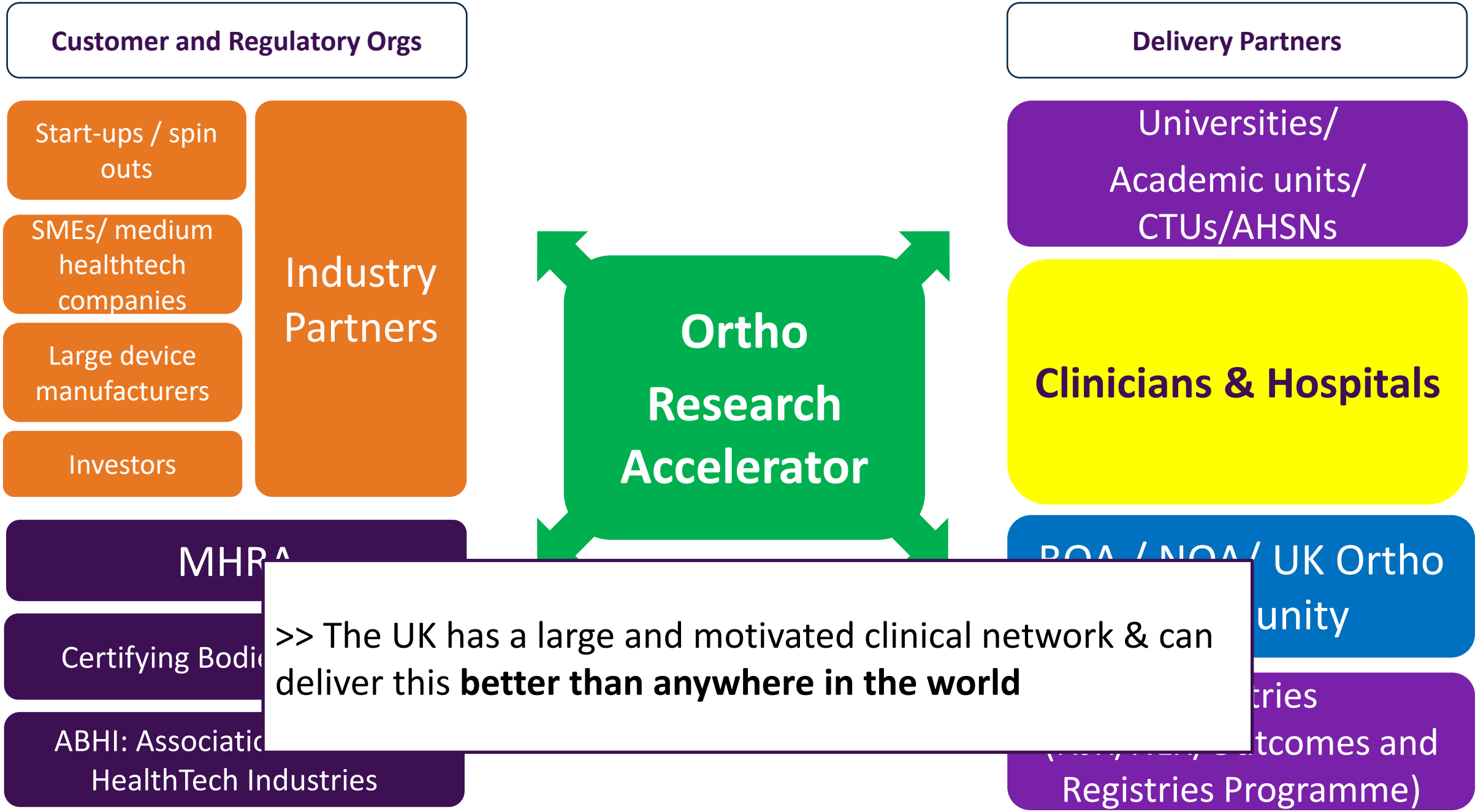
Academic and Clinical Network

- **UK-wide clinical & academic expertise**

One-stop for commercial/early phase research

- Project delivery teams
- Regulatory advice
- Health economics & value propositions
- Healthcare procurement insight




Customer and Regulatory Orgs
Delivery Partners
Start-ups / spin outs
SMEs/ medium healthtech companies
Large device manufacturers
Investors
Industry Partners
Ortho Research Accelerator
Universities/ Academic units/ CTUs/AHSNs
Clinicians & Hospitals
MHRA
Certifying Bodi
ABHI: Associatio HealthTech Industries
UK Ortho unity
tries
tcomes and Registries Programme)
>> The UK has a large and motivated clinical network & can deliver this **better than anywhere in the world**

What next……

Why?

- **Establish the UK as the best place** to do early device research at pace
- **Improve UK access to new devices** and technologies; support SMEs to develop and launch new products; Retain UK innovators & start-ups
- **Using expertise that is already in the UK** to deliver high quality data
- Be ready for a **new wave of Digital/Artificial Intelligence** technologies

What?

Innovative approach to the problem

- UK collaborative research accelerator
- Supported by ABHI, NICE, MSK Charities and others
- In development >> in discussion with Government & others about funding