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TRANSFORMING UK CLINICAL RESEARCH

Clinical Research Coalition: Methodology related to economic impact assessment

About the Clinical Research Coalition

The Clinical Research Coalition (CRC) is an independent community of thought leaders from the clinical research, industry, regulatory and governmental sectors. The report and evidence sessions were chaired by The Baroness Blackwood of North Oxford and Dr Jonathan Sheffield. The views in this document are collaborative, confidential and independent.

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Current state of clinical research

The UK contributes 3 per cent of the global participants recruited into clinical trials (Office for Life Sciences, 2019), equating to 732,176 in 2020 (NIHR, 2021). Despite positioning the UK at the forefront of European clinical research, this figure is but a fraction of what could be achieved by implementing the transformation strategy that is set out below.

Of the 732,176 participants, 28,832 were recruited into commercial trials (NIHR, 2021). The economic impact of such trials is more substantial than non-commercial trials, with the NHS receiving an average of £9,189 from life science companies per commercial participant (KPMG, 2019). Our economic assessment highlights a transformation strategy comprising of 11 recommendations outlined within the Coalitions Interim report, created in 2020. The recommendations fall into two distinct categories, which will drive growth in the total number of research participants in the UK. Furthermore, the strategy will catalyse a paradigm shift towards late-stage trials, as these offer the greatest economic upside.

The UK performs well in Phase I clinical research because early-stage trials require technologically advanced infrastructure and methods. Conversely for late-stage trials, life science companies often look to countries in which it is cheaper to run clinical trials, and with more efficient infrastructure to conduct commercial research. Figure 1 shows the latest data (2017 and 2018) on new trials started across the globe (ABPI, 2019; ABPI 2020).

2017

Rank	Country	PI	Country	PII	Country	PIII
1	US	614	US	970	US	528
2	China	194	UK	253	Germany	276
3	UK	147	Germany	232	Canada	259
4	Germany	136	Japan	227	Spain	258
5	Japan	111	Spain	204	UK	243
6	Australia	82	France	176	Poland	243
7	Canada	72	Canada	176	Italy	235
8	France	52	Italy	141	Japan	235
9	Spain	49	China	122	France	120
10	Italy	19	Australia	112	Australia	180
11	Poland	15	Poland	98	China	146
12	Switzerland	14	Switzerland	30	Brazil	116
13	Brazil	10	Brazil	23	S Africa	72
14	S Africa	5	S Africa	17	Switzerland	65
Total		**1,520**		**2,781**		**2,976**
UK share		9.7% (% of global PI)		9.1% (% of global PII)		8.2% (% of global PIII)

2018

Rank	Country	PI	Country	PII	Country	PIII
1	US	526	US	1021	US	626
2	China	234	UK	268	Germany	315
3	UK	95	Germany	249	Spain	308
4	Germany	68	Spain	221	UK	292
5	Australia	66	France	200	France	290
6	Japan	66	Japan	198	Canada	289
7	Spain	49	China	190	Italy	264
8	Canada	43	Canada	187	Poland	250
9	Belgium	39	Italy	157	Japan	242
10	France	37	Australia	152	China	219
11	Italy	20	Poland	133	Australia	211
12	Poland	10	Belgium	125	Belgium	208
13	S Africa	6	Hungary	74	Hungary	177
14	Switzerland	6	Switzerland	56	Brazil	123
15	Hungary	2	Brazil	37	Switzerland	101
16	Brazil	0	S Africa	20	S Africa	77
Total		**1,267**		**3,288**		**3,992**
UK share		7.5% (% of global PI)		8.2% (% of global PII)		7.3% (% of global PIII)

Figure 1: new commercial trials

The UK is underperforming in Phase III clinical research and lags behind the US, Germany and Spain, with France and Canada not far behind. Clinical trials in the UK are inefficient and slow, with various blockers existing to stall progress. Eliminating these blockers will drive investment into the UK by life science companies, ultimately increasing income to the NHS, Gross Value Added (GVA) related to clinical trials and jobs associated with the industry.

One such blocker is accessibility to patients for clinicians and researchers, as limits on data sharing and data quality hinder the recruitment process. Furthermore, the same is true in the reverse direction; many patients are unaware of relevant trials in which they could partake in. 1 in 17 people in the UK have a rare disease, equating to 3m people, yet 95 per cent of rare diseases lack treatment. Genetic Alliance UK found that most of these individuals have a very positive attitude to partaking in trials; if an online portal is created for patients to easily view trials that may be relevant, as well as a portal for clinicians and researchers, participant numbers could be increased dramatically. Solutions to other blockers are detailed in the transformation strategy below.

Transformation strategy

Transforming UK clinical research to alleviate blockers, enhance efficiency, broaden recruitment and ultimately make the UK more attractive to life science companies requires a focus on two key areas: operational efficiency and increasing participation. The first is the engine, while the second is the fuel needed to power the engine. The CRC has outlined 11 recommendations that fall into these distinct categories.

Operational effectiveness

R1
The Medicines and Healthcare Products Regulatory Agency (MHRA) and Health Research Authority (HRA) should continue their progress towards a single combined application dossier to reduce the administrative burden placed upon researchers looking to initiate health and care research. They should also stratify applicant health and care research according to risk, with lower-risk research needing only lighter – and faster – scrutiny. They should aspire to a long-term goal of a 15-day approval standard for simple protocols and a 30-day standard for those that involve complex, innovative design. Researchers also have a role to play by developing shorter, simpler protocols whilst maintaining compliance with international standards.

R2
A UK Health Emergencies Research Planning Group should be established; led by the NIHR, with support from the Clinical Research Networks, Biomedical Research Centre Network, Clinical Research Facilities, MRC/NIHR Trial Methodology Research Partnership, UKCRC CTUs and Applied Research Collaborations and funded by multiple agencies. It should include the appropriate organisations from the devolved nations to ensure it is taking a UK-wide approach. This would develop innovative, adaptive research plans with clear structures and groups that mobilise health and care research platforms instantly on a standardised UK-wide basis in the event of a pandemic, bioterrorism or other threat.

R3
The Government must fulfil its manifesto commitment of spending 2.4 per cent of GDP on R&D by 2027. It should also commit to funding uplifts for vital elements of the research ecosystem, such as the NIHR, HRA, HDR UK and Quality-Related funding to universities. A more prominent focus (including more funding) for applied research, and its closer integration with trials is required to expedite the translation of trial evidence into widespread practice across varied contexts.

R4
The UK should move from being a 'participatory' country to being a landmark registration country, running full registration studies. The ambitious plans of the MHRA to accelerate licensing and start-up in a post-Brexit world must be supported by collaboration between commercial research organisations, industry, academia, the NHS and Government.

R5
The medicines' access and uptake environment are a critical driver of global inward investment, including in research. However, the NHS is frequently cited as having a culture of 'slow and low' adoption of innovation, and actions to overcome this have been delayed by Covid-19. As the UK builds its roadmap to recovery, progress must be made towards the objective of the UK being in the top quartile of comparator countries for speed of adoption and overall uptake of innovative medicines.

Increasing participation

R6
There remains a pressing and immediate need to prioritise the restart of non-Covid-19 clinical trials, many of which remain paused. Clinical capacity is often cited as the leading reason for failure to restart clinical trials. As such, the NHS should look to make additional use of independent-sector capacity to support its recovery and enable clinical research to restart immediately.

R7
A single national online data-enabled find, recruit and follow-up service for use by clinicians and researchers should be developed – incorporating a wide range of datasets – enabling a streamlined approach to identifying individuals and cohorts of patients. This would facilitate the 'Right to Write', enabling researchers and clinicians to search clinical records and directly contact patients who might be suitable for a clinical research relevant to their condition. This would be targeted at those who have indicated consent under

Recommendation 3, once the patient consent model has achieved sufficient critical mass. This online portal should be centrally funded from the 2020 Comprehensive Spending Review.

R8
Alongside the national find, recruit and follow-up service for clinicians and researchers, there should be a single national online portal for patients to access research options in all healthcare conditions and regions across the UK, building on initiatives such as the National Institute for Health Research (NIHR) Be Part of Research, or in Scotland, Register4Share, as well as charity initiatives such as Join Dementia Research. It should be accessible, user-friendly and designed specifically with patients and the public in mind.

R9
Currently, researchers need to ask permission from all the data controllers for onward data sharing. Yet there are good reasons for onward sharing of data, including checking validity, supporting meta-analyses, and designing future research. There should be delegated authority to act on behalf of multiple data controllers and share information as required, taking a balanced approach to risk, building on the work of the HDR UK Data Alliance.

R10
The extensive but uncoordinated potential of UK health and care data should be unlocked. To do this there should be a single cross-Governmental National Health and Care Data Strategy to overcome the lack of connectivity between datasets, building on the work of HDR UK Hubs and NIHR Health Informatics Collaboratives (HICs). This should include data sets at primary, secondary, tertiary, community and social care level, including those owned by local authorities. This should be linked to the single UK online portal for research outlined in Recommendation 4. Alongside this, there should be a consistent, standard approach to the governance, process and contracting for access to real-world data to simplify the process and ensure alignment between the many organisations within the NHS.

R11
The UK Government should promote the UK as a global leader in the design and delivery of innovative health and care research, with unique propositions such as NHS Data, Integrated Care Systems, Genomics England, UK Biobank, HDR-UK Hubs, NIHR Bioresource, an independent MHRA, NICE, quality-assured UK Clinical Research Collaboration, Registered Clinical Trials Units network, and MRC/NIHR Trial Methodology Research Partnership. The clear pathway from research to patient access achieved through partnership working across MHRA, NICE, NIHR and the NHS should also be promoted.

Impact of transformation strategy

The first five recommendations (R1 – R5) will support UK clinical trials to operate more effectively. R1 aims to reduce approval times from 80 days to 15-30 days, which will make the UK more competitive in the global commercial trials market; currently, the UK is five times slower than the US and twice as slow as Poland at setting up trials. Yet R1 alone is not a complete solution to the slow set-up time in the UK, as maximising operational effectiveness requires efficiency throughout the entire trial process. R2 would enable the UK to rapidly deploy clinical research infrastructure in the event of an emergency situation; as such, more trials would be conducted in the UK. R4 would accelerate licensing and the start-up of trials, while R3 and R5 would break the UK's reputation as being slow at expediting trial evidence into practice and adopting innovative treatments into the NHS. If life science companies knew they had a fast route to market, they would be more inclined to conduct research in the UK.

The remaining recommendations, R6 – R11, would increase participant recruitment. R6 highlights the importance of restarting non-covid-19 trials, as continued stalling will result in companies pulling their research from the UK in favour of other countries and make the UK less attractive for investment. Building central portals for clinicians, researchers and patients, as outlined in R7 and R8, would hugely improve accessibility to patients and trials. R9 and R10 would make data sharing more efficient and ultimately increase engagement with, and recruitment into, clinical trials.

Projecting UK clinical research

Total participants

To project the impact of the transformation strategy on total participants, we have assumed that alleviating blockers and enhancing efficiency will increase the participation rate to that of the UK's competitors, as a percentage of the population. 1 per cent of the UK's population participate in clinical trials per year, compared to 3 per cent of the US' population. Moreover, the UK's share of global participants is 3% (Office for Life Sciences, 2019), whereas the US' is 40 per cent (KPMG, 2019). Leading the world in clinical research, the US offers a sensible target for the number of participants recruited into trials as a percentage of the population. In the UK, this would equate to 2m participants per year. Note that Spain holds a 4 per cent share of global participants (Office for Life Sciences, 2020) and with a population of 47m, it outperforms the UK where 2 per cent of its population are recruited into trials per year. An alternative approach is to look at the number of hospital admissions per year and assume that a certain percentage of those could be recruited. 17m patients in the UK were admitted to hospital in 2018/19 (NHS Digital, 2019); assuming a 15 per cent recruitment rate, 2.6m patients would participate in trials. Taking an average of the two methods gives 2.3m participants, which increases to 3m over 5 years considering the 5.7 per cent Compound Annual Growth Rate (CAGR) for clinical research (Grand View Research, 2021).

Commercial participants

The transformation strategy focuses on making the UK more attractive to life science companies for late-stage clinical trials. We are assuming that each recommendation would increase the UK's global share by 0.25 per cent, 0.5 per cent and 0.75 per cent for Phase I, Phase II and Phase III commercial trials respectively. As such, the strategy will shift the UK towards late-stage research, as these trials offer more value from an economic standpoint. Upon requesting data from the NIHR, we found that in 2019/20 an average of 19, 33 and 141 participants were recruited per Phase I, Phase II and Phase III trial respectively. Furthermore, we project that the transformation strategy will increase the UK's share of new global commercial clinical trials to 10.25 per cent, 13.65 per cent and 15.56 per cent for Phase I, Phase II and Phase III respectively; this corresponds to 186,716 commercial participants per year (Figure 3).

Method 1: Projecting Based on the US (Global Leader)	
US Clinical Research	
US Population	330,000,000
Total Participants	9,762,347
Total Participants / Population	2.96%
Current: UK Clinical Research (Total)	
UK Population	68,000,000
Total Participants	732,176
Total Participants / Population	1.08%
Target: UK Clinical Research (Total)	
Total Participants / Population	2.96%
UK Population	68,000,000
Total Participants	2,011,635
Total Participants Added	1,279,459
Method 2: Projecting Based on Hospital Admissions	
Finished Admission Episodes	17,100,000
% Recruited to Trials (Target)	15%
Total Participants	2,565,000
Total Participants Added	1,832,824
Average (Method 1/2)	
Total Participants	2,288,318
Total Participants (After 5Y @ CAGR)	3,019,195
Total Participants Added (5Y @ CAGR)	2,287,019

Figure 2: projecting UK capacity for clinical trials

New Commercial Trials in UK / Year			
	PI	PII	PIII
2017 UK Share (% of Global)	9.67%	9.10%	8.17%
2017 UK Number of Trials	147	253	243
			643
2018 UK Share (% of Global)	7.50%	8.15%	7.31%
2018 UK Number of Trials	95	268	292
Impact of Recommendations			
Increase in UK Share (p/rec)	0.25%	0.50%	0.75%
Increase in UK Share (11 rec)	2.75%	5.50%	8.25%
UK Share (% of Global)	10.25%	13.65%	15.56%
UK Number of Trials	130	449	621
Total Commercial Trials in UK / Year			
New Commercial Trials (% of Total Commercial)			56%
	PI	PII	PIII
Total Commercial Trials	231	799	1,106
			2,136
Commercial Participants	4,392	26,367	155,957
			186,716

Figure 3: projecting UK capacity for clinical trials

Economic impact

Clinical research in the UK generates an annual GVA (Gross Value Added) of £2.7bn and supports 47,467 FTE jobs (KPMG, 2019). We have assumed that the total number of participants is related to the size of the clinical trials industry; as more participants are recruited into trials, it is likely that GVA and the number of FTE jobs will also rise. Historical trends in total participants (KPMG, 2019), GVA and FTE jobs indicate that for every participant added, £455 of GVA and 0.002 FTE jobs are generated (Figure 4).

The transformation strategy would drive participation to 3m people per year, adding 1.3m to the current number of total participants. This represents an additional £1bn in GVA, increasing total GVA to £3.7bn, and 3,800 FTE jobs (Figure 5). On average, the NHS receives £9,189 per commercial participant from life science companies. Assuming that this value remains constant in the future, the NHS would receive a total of £1.7bn per year from commercial research. This would be an increase of £1.4bn per year as a result of driving up the number of commercial participants from 28,832 to over 180,000.

% Change in Total Studies (Last 3 Years)	30%
Increase in Total Studies (Last 3 Years)	1,816
% Change in Total Participants (Last 3 Years)	30%
Increase in Total Participants (Last 3 Years)	219,653
Increase in Total FTE Jobs (Last 3 Years)	365
Increase in Total GVA (Last 3 Years)	£100,000,000
Total GVA / Total Studies	£55,078
Total GVA / Total Participants	£455
Total FTE Jobs / Total Participants	0.002

Figure 4: historical trends in UK clinical research

Participants added		£ to NHS	GVA	FTE Jobs
Total	Commercial	Added	Added	Added
2.3m	187k	£1.4bn	£1bn	3,800

Figure 5: the economic impact of transforming UK clinical research

Assumptions

1. The average number of commercial participants in Phase I, Phase II and Phase III trials will remain constant in the future
2. The increase in participants (L3Y) led to an increase in GVA
3. A future increase in participants will increase GVA at the same rate
4. The increase in participants (L3Y) led to an increase in FTE jobs
5. A future increase in participants will increase FTE Jobs at the same rate
6. The US' total participants (as a % of population) is a target for the UK
7. 15% of hospital admissions could result in clinical trial participation
8. Each recommendation will increase the UK's global share by 0.25%, 0.5% and 0.75% for Phase I, Phase II and Phase III commercial trials respectively
9. Income to the NHS per commercial participant will remain the same in the future
10. Income to the NHS per commercial participant averages out at £9,189 across all three phases of trial
11. The number of new commercial trials in 2018 (latest data) is representative of the annual number of new trials in the future

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