UK Clinical Trials Talent Taskforce (UK CTTT)

Terms of Reference

Document Contents

JOINT CHAIRS

- Angela Topping – NHS R&D Forum Executive and Head of Newcastle Joint Research Office (NJRO)
- Jacqueline Johnson North – Chief Executive of IAOCR (International Accrediting Organisation for Clinical Research) and GCSA (Global Clinical Site Accreditation)

AMBITION

- Provision of a best-in-class holistic ecosystem for clinical trials talent attraction, development, professional recognition and retention to support the UK's desire to be a world-class destination for clinical research.
- Utilise existing products and services from the UK's expert provider network to "grow our own" talent; leveraging and supporting high-quality solutions from both UK commercial and UK non-commercial solutions providers to fast-track a comprehensive solution that is beneficial for all key stakeholders

CONTEXT/BACKGROUND

This Taskforce will work in support of a shared ambition to attract, develop, recognise and retain a world-class clinical trials workforce, which is essential to achieving the aspirations and objectives detailed in the following recently published Government documents:

- Commercial Clinical Trials in the UK – Lord O'Shaughnessy (26 May 2023)
- Pro-innovation Regulation of Technologies Review, Life Sciences and HM Government Response to Professor Dame Angela McLean's Pro-Innovation Regulation of Technologies Review Life Sciences (26 May 2023)

Lord O'Shaughnessy's review on Commercial Clinical Trials in the UK calls for "exceptional best practice" to become the norm so that patients, the NHS and the UK as a whole can benefit. The report states "We can do so much better than we currently are, and everything I have heard from clinicians, patients, researchers, NHS bodies, industry and others during the course of this review reveals a strong desire to regain our world-leading position in this area." Lord O'Shaughnessy has proposed that the government should aim to double the numbers of people taking part in commercial clinical trials in the next 2 years, and double it again by 2027.

HM Government Response to Professor Dame Angela McLean's Pro-Innovation Regulation of Technologies Review, Life Sciences accepts the recommendation to create "…a skills pipeline across those regulators whose remits cover life sciences to build expertise in the long term, including through the use of industry secondments, Centres of Excellence in Regulatory Science and Innovation (CERSIs)…". It also states "The government recognises that in recent years there has been a loss of in-house talent out into the private sector, therefore the government will commit to looking at a secondments programme not only from the private sector but from across UK academia to promote regulatory research and innovation… The CERSI model has proved effective in the United States, in providing additional expertise to the regulators and the wider system, we will look to convene a similar network of expertise here, building on the UK's outstanding academic science base and building a sustainable pipeline of talent for the future."

To achieve the ambition set out by Lord O'Shaughnessy and support the recommendations in his report, a world-class workforce is needed to enable world-class clinical trials. Additionally, the outcomes of this Taskforce can support the primary aim of the Pro-Innovation Regulation of Technologies Review, Life Sciences, "to establish the UK as the best regulated economy in the world in key growth sectors ensuring that industry and investors have the certainty then need to drive innovation, investment and growth through anticipating new developments in emerging technologies" through the establishment of best-in-class talent processes in the UK where talent can be shared through structured secondments.

Whilst many employed in the sector have already received good quality competence development, the current landscape of opportunities:

- Is hidden from many – with students not knowing about clinical research as a viable career option.
- Proves difficult for early talent to identify and navigate career pathways.
- Contains a plethora of training and education options, varying in length, quality, fees, and outputs – making it difficult for individuals and organisations to identify appropriate, high quality options.

- Is generally split between NHS and commercial opportunities (secondment opportunities would facilitate breadth of understanding and further competence development).
- Can be repetitive – sometimes taking a "sheep dip" approach to training, which can be frustrating to individuals, as well as costly to employers.
- Can lead to competence gaps due to assumptions being made that individuals are competent because they have been working in research for a stipulated number of years.
- Unlike other regulated industries, contains no clear, industry-wide accepted competencies, career pathways or routes to professional recognition.

SCOPE AND OUTPUTS

This Taskforce will focus purely on the roles of clinical trial site staff working in the NHS or commercial sector in the UK. However, the Taskforce should also take into account the recommendations in Professor Dame Angela McLean's Pro-Innovation Regulation of Technologies Review, Life Sciences, with particular regard to developing "…a skills pipeline across those regulators whose remits cover life sciences to build expertise in the long term, including through the use of industry secondments". In this regard recommendations on how industry secondments utilising clinical trial sites and site staff might best work should be considered.

In the spirit of Lord O'Shaughnessy's report and in support of it, the purpose of this Taskforce is to:

- Seek out existing work that has been completed or is currently in development across the whole of the UK clinical trials landscape.
- Identify best-in-class solutions across the whole of the UK : England, Northern Ireland, Scotland, Wales.
- Make recommendations for a joined-up best-in-class ecosystem (encompassing both public and private sector) to support cradle to grave career pathways. Regional differences and levelling-up recommendations will also be included.

- Provide a gap analysis and recommendations for development of new solutions, where existing high-quality solutions do not already exist
- Consider the recommendations HM Government Response to Professor Dame Angela McLean's Pro-Innovation Regulation of Technologies Review, Life Sciences, with particular regard to secondments.
- Deliver a report containing recommendations and an action plan to the industry and to UK Parliamentarians

OUT OF SCOPE

- Ideas and proposals for new solutions. Solutions that are not already in existence or in development.
- Work from providers outside of the UK – breadth of scope is key to keeping this initiative manageable.
    - NOTE : Work from outside the UK may be utilised for benchmarking purposes, but cannot be submitted as a potential solution (please note that all work used for benchmarking and other purposes must be fully referenced and respected).
- Generic (non-industry-specific) management/leadership training programmes/courses/education/qualification/accreditation programmes
- Generic (non-industry-specific) skills development training/courses/education/qualification/accreditation programmes e.g. time management, project management, etc.
- Solutions not related to the attraction, development, recognition or retention of clinical trial site staff.
- Proposals for attraction, development, recognition and/or regulatory of regulatory staff can be included, provided the proposal is also linked to clinical trial site staff.
- Academic education e.g. PhD. This Taskforce is focused on education up to degree level, in addition to developing pragmatic, workplace-based competencies

TIMELINE

The taskforce will work rapidly through 6 “Sprint” stages as follows:

Sprint Stage	Sprint Deliverables Summary	Completion Deadline
1	Taskforce & Systems Setup (Including Taskforce Member Registration Form)	DATES
2	UK Ecosystems Survey(s) Setup	TO BE
3	UK Ecosystems Survey(s) / Information Gathering	AGREED
4	Sub-Taskforce Leaders Review Survey Results and Information + Submit Recommendations to Joint Chairs	WITH
5	Joint Chairs Consult with Sub-Taskforce Leaders and Write Draft Report	SUB-TASKFORCE
6	Final Report Published + Industry and Parliamentary Consultations Commence	LEADERS

SUB-TASKFORCES

To facilitate working at pace, the work of this Taskforce is split across eight Sub-Taskforces. Each Sub-Taskforce will be co-lead by two or three clinical research professionals with expertise specific to the area they are leading on. To facilitate balance, the leads in each Sub-Taskforce will be appointed from different organisations.

1. Pre-Employment : Clinical Research Experience Opportunities and Education (up to and including first degree level – QCF* Level 6 max.)	**2. Early Talent Pipeline : Attraction, Recruitment and Gateways into a Clinical Research Career**	**3. Early Talent Pipeline : Onboarding, Development & Retention (including apprenticeships)**	**4. Experienced Talent : Attraction, Career Development & Retention (including transferable skills and secondments)**
5. Competence Frameworks for Clinical Trial Site Staff (focusing on competencies specific to clinical research)	**6. Competence Acquisition and Development : ICH-GCP (including, but not limited to training programmes)**	**7. Competence Acquisition and Development : Clinical Research Skills (including, but not limited to training programmes)**	**8. Competence Verification, Accreditation & Professional Recognition (non-academic, pragmatic standards –QCF* Level 3 approx.)**

*QCF is the UK Qualification and Credits Framework

COMMITMENT

It is anticipated that each Sub-Taskforce Leader will need to contribute approximately 16 hours of their time over a two month period. Additionally, Taskforce Members will be invited to attend the IAOCR Clinical Research Industry Leaders Think Tank on "Working Together to Deliver a World-Class Destination for Clinical Research" on 9 November at The Spine, Liverpool. However, participation in the Think Tank is optional.

Date & Time	Approx. Commitment	Location	Purpose
DATES TO BE	2 hrs	Online Meeting & Follow-Up	Taskforce Kick-off Meeting : Scope of Work, Review Online Survey, Gather Feedback from Taskforce, Agree Action Plan for Communication to Wider Clinical Research Community, Next Steps
AGREED	4 hrs	Each Sub-Taskforce to agree own action plan	Identify service providers / experts and encourage completion of online survey.
WITH	8 hrs	Each Sub-Taskforce to agree own approach	Sub-Taskforce Leaders Review Survey Results and Information + Submit Recommendations to Joint Chairs
SUB-TASKFORCE	2 hrs	Telephone / Email / Online	Consultation with Joint Chairs + Report Review Period
LEADERS	-	-	Final report published.
9 November	Full day (optional Think Tank & networking)	The Spine, Liverpool	All Taskforce Members are invited to participate in IAOCR Clinical Research Industry Leaders Think Tank

SYSTEMS AND SUPPORT

- IAOCR will provide a Taskforce Administrator to support meeting coordination, etc.
- IAOCR will provide marketing support, to work with the Sub-Taskforce Leaders to promote the taskforce survey, etc.
- IAOCR's website will be utilised to collect online survey information.
- IAOCR will provide the Sub-Taskforce Leaders with access to an online project management tool where information and documents related to this Taskforce can also be accessed and shared.

ETHICS, COMMITMENT AND SPIRIT

- The Chatham House Rule will apply https://www.chathamhouse.org/about-us/chatham-house-rule
- Everyone will work professionally and in the spirit of openness, honesty and collaboration. The number one focus is to find a holistic best-in-class solution for the UK clinical trials industry, utilising existing solutions from UK suppliers. Personal interests and views will be put aside.
- The purpose of the Taskforce is to seek out *existing* best-in-class solutions available from UK experts/providers/networks. Every applicable person and organisation (commercial or non-commercial, business, individual, etc) should be invited submit best-in-class solutions. No UK person, organisation, group, network, etc. should be excluded.
- The survey / information gathering will focus on publicly available/published information only. No product / service provider should be asked to provide any information that is not in the public domain.
- The ethos of this Taskforce is to seek out best-in-class solutions to enable a joined-up UK ecosystem of best-in-class service providers with win:win outcomes for UK clinical research and the supply chain that supports and enables research. Individuals, organisations (commercial and non-commercial), networks, groups, etc. take great pride in their work and are invested heavily in their products and services. Respect must be given to everyone's time, expertise, intellectual property, etc. All contributions are valuable and must be valued.

- Everyone – individuals, organisations, networks, groups, etc. that contribute in a meaningful way to the Taskforce must be recognised for their contribution in the final report. When reading the draft report, Sub-Taskforce Leaders must check to ensure that all contributions in their Sub-Taskforce area appropriately recognised.
- All Taskforce Joint Chairs and Sub-Taskforce Leaders must document any conflicts of interest/potential conflicts of interest in the Taskforce Member Registration Form

REMUNERATION AND EXPENSES

- There is no budget for expenses. Meetings may be attended in person or via web meeting. In the event of face-to-face meetings each person /organisation will cover their own costs.
- Members will contribute their time and expertise on a voluntary basis.

RECOGNITION OF CONTRIBUTION

Members will be referenced in the final report and in promotional material about the Taskforce in recognition of their contribution. They may, where available also be invited to participate in online activities, speaker opportunities, conferences, events, press releases, etc.

CONFIDENTIALITY

All Taskforce Members will sign a Non-Disclosure Agreement and complete a Taskforce Member Registration Form.