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British In Vitro Diagnostics Association

BIVDA Briefing – UK Clinical Research Delivery Plan

A new policy paper has been drafted on the Future of UK Clinical Research Delivery, an implementation plan to set out an ambitious vision of how this research will materialise. The aim of the vision is to turn the promise of cutting-edge UK science, from genomics to novel cancer vaccines, into real improvements in disease prevention, diagnosis and treatment. The plan covers the timeframe for 2021 to 2022, and addresses study set-up efficiency, building upon digital platforms, innovative research designs, making research matter to the NHS and strengthening public, patient and service user involvement in research.

There is important collaboration taking place between various health groups, the NHS, patients and public to aid the delivery of the plan. Regulators, medical research charities and partners from across industry will be overseen by the UK-wide Clinical Research, Recovery, Resilience and Growth (RRG) programme. The plan is also building upon existing commitments and priorities set out in the NHS Long Term Plan, the Life Science Sector Deals, A Healthier Wales and the framework for NHS Scotland.

Key commitments described in this text include the delivery of a UK-wide programme of work to drive the managed recovery of multi-site studies over the next 12 months, continuing existing commitments to make UK clinical research delivery easier (a HRA Rapid Research Ethics Committee review which builds upon the use of the Integrated Research Application System (IRAS)) and further steps regarding the digitisation of the clinical research process, to make it faster and cheaper. Expansion of flexible workforce and delivery models, including capacity for research in primary and community care, are among the tasks to be undertaken also.

The plan proposes a joined-up system – where sponsors of both commercial and non-commercial research can easily deliver studies across the UK and patients anywhere in the country can easily participate. Regarding England, a new 'Find, Recruit and Follow-up' service is to be initiated. This tool will facilitate the connection of researchers with the digital tools and platforms that will expedite research recruitment, set-up and monitoring. Creating this

service will be a major move towards unlocking the power of data to drive research, alongside NHSX's Health and Social Care Data Strategy and the National Data Strategy (NDS), published in September 2020. The NHS Innovation Service will be established and use 'demand signalling; to communicate the needs of the NHS in England. New treatments and technologies will be researched rapidly by innovators and researchers to assess the potential of their addressing pressing healthcare challenges.

- Regarding action area 1 'improving the speed and efficiency of study set-up', NHSEI, NIHR and HRA will work with devolved administrations to design and implement a national contract value review process for commercial contract research. NIHR will work with the devolved administrations to ensure the development of digital solutions that link research approvals portals with delivery management systems where linked systems are not already in place. The Innovative Licencing and Access Pathway (ILAP) will continue to provide an integrated UK approach to accelerate time to market.

- Action area 2 aims to build upon digital platforms to deliver clinical research. The RRG programme will work to develop a seamless UK-wide system of digital platforms for research sponsors. NHS DigiTrials in England will automate and develop the sophistication of their feasibility, recruitment and outcomes services to increase both capacity and speed.

- Action area 3 aims to increase the use of innovative research designs. This will be achieved through enhanced early engagement support for researchers from the MHRA. The RRG programme will lead work to understand the barriers and enablers facing researchers in delivering patient centred, innovative research designs as standard.

- Action area 4 seeks to align research programmes with needs of the UK health and care systems. NIHR will work on this objective by developing the professional identity, standards and regulatory accountability for clinical research practitioners and further develop the Associate Principal Investigator role. The expansion of flexible workforce and delivery models falls under this area also.

- Action area 5 addresses improving the visibility and making research matter to the NHS. It will made clear to all staff the different ways to get involved in research and increase awareness of the value of research and innovation. Recognition of the professional contribution of healthcare staff will be boosted, and the value of research and innovation among NHS leaders. NIHR, on behalf of the UK, will engage with regulatory bodies for registered professionals around the inclusion of research delivery activity in standards and revalidation requirements.

- Action area 6 relates to making research more diverse and relevant to the whole of the UK. NIHR will develop systems and processes that enable health research to be supported within areas and communities traditional under-served by research, (e.g., by ethnicity, geography or deprivation), to tackle health inequalities. NIHR, NHS Digital and the devolved administrations will scope the use of national datasets to analyse the diversity of research participants. Guidance to increase diversity n studies will be developed by MHRA and HRA. HRA will automatically register clinical trials in a public registry, unless the sponsor has permission to delay this to a later stage, starting with trials of medicines.

- The last action area, number 7, supports the strengthening of public, patient and service user involvement in clinical research. This will be improved through community engagement with patients and communities to shape priorities and study designs for research. The UK will work to address practical barriers to enable increased and easy-to-administer involvement of the public, working with key partner organisations. The

RRG programme will draw on this work to addresses barriers and enablers of behavioural change to deliver patient-centred research designs.

Phase 1 of the plan is now underway, with partners of the RRG board beginning to carry out the above actions. Strategic direction will be provided by an oversight group chaired by the Department of Health and Social Care (DHSC) Minister for Innovation and composed of senior representatives from our partner organisations, industry, medical research charities and the NHS.