



Trends Shaping the Future of Clinical Trials

How the UK can use innovation to build a
world-leading clinical trials sector.

A white paper by Microsoft

 Microsoft

The future of clinical trials





Introduction

The Covid-19 pandemic caused unprecedented disruption to societies across the globe, with whole countries entering national lockdowns and governments placing unparalleled restrictions on communities and industries. One widely recognised impact of this disruption was the acceleration of digital transformation, with businesses taking a quantum leap forward in their adoption of digital tools.¹ The transformation in the ways companies do business and in customer expectations is seen across sectors and is largely expected to last.

In the life sciences industry, digital tools are being used to radically reimagine how clinical trials are designed and executed.² Decentralised trials (DCTs) operate by making some or all of the trial remote, virtual, and in some cases site-less. Hybrid trials seek to optimise the use of Real-World Data (RWD), through either remote monitoring tools or analysis of electronic health records. These new instruments being used to innovate trials are receiving widespread support from both

government and industry, as their potential benefits are beginning to be more widely recognised and valued.

The UK's Covid-19 RECOVERY³ and PRINCIPLE⁴ trials are a good example of innovative methodologies that bring together data sets from different sources from across the NHS for central analysis, and mobilise decentralised forms of patient recruitment and management. The trials are widely recognised as a major success, enabling the discovery of life-saving treatments for Covid patients at unprecedented speed. The trials have their roots in the NHS DigiTrials initiative⁵, which was established under the leadership of Professor Sir Martin Landray to develop and implement new digital approaches to clinical trials, and in the ORION-4 trial⁶ that was based on these principles. At a European level, the UK was selected as one of the countries to run the RADIAL trial, a pilot trial under the IMI's Trials@Home programme for decentralised clinical trials.⁷

“The UK has a great opportunity to build on its research response to the COVID-19 pandemic, where the country enabled and delivered ground-breaking research at pace and scale that has had international impact, saving lives in the UK and around the world”

Nick McNally, Managing Director Research at UCLH/UCL & Chair UKRD



Despite these recent success stories, clinical trials in the UK have been in decline for several years, even before the pandemic's effects. Data published by the Association of British Pharmaceutical Industry (ABPI) shows that between 2017 and 2020 clinical trial activity in the UK decreased by 24%.⁸ Moreover, the UK's recovery in clinical trials since the pandemic has been slower than many of its international counterparts, and figures show that the UK has dropped in the international rankings for clinical trials across all phases since 2018.⁹ To achieve the aim of becoming a global leader in clinical research, the UK will need to leverage the potential of technology to increase the number and efficiency of trials, to recruit more NHS patients onto trials, and to transform the cost profile of undertaking clinical trials.

The UK is well positioned to meet this challenge, given the nature of the UK health system. The NHS is a single centralised system, placing it in the almost unique position of possessing the data of millions of patients. In this single system, health research and delivery are well integrated, with researchers and clinicians working in close proximity across many hospital trusts, which in turn are part of world-leading research centres.

“The UK has much greater opportunity for advancing clinical research than many other international health systems, as its centralised nature enables it to conduct clinical research at scale, when compared to the more diffuse and fragmented health systems typically seen elsewhere.”

Amir Kalali, Co-Chair of the Decentralised Trials and Research Alliance (DTRA)

There is a considerable opportunity for the UK to host a world-leading clinical trials industry. In this paper, we lay out the trends, supporting technologies and challenges in deploying digitally-enabled clinical trials, along with what the UK government is doing to address these challenges. We look at a vision for the future, and how Microsoft and our partners are helping make that vision a reality.

“Clinical trials are important for patients, they are beneficial to the NHS and they are good for the UK economy. By embracing new and innovative approaches in research we have the opportunity to transform how clinical trials are conducted in the UK and maximise the benefits for the NHS, patients and the economy.”

Richard Torbett, CEO, Association of the British Pharmaceutical Industry



Macro trends impacting the clinical trials landscape

Over recent years, several trends have emerged that are impacting how clinical trials are designed and carried out:

1. Precision Medicine

The development of new medicinal therapies is increasingly focused on specialised drugs, either for rare diseases that have small patient populations or complex molecules designed to support specific cohorts based on their characteristics. This creates challenges when conducting clinical trials, as they require more complex inclusion criteria for patients taking part in the trial or have smaller patient populations from which to select patients. Digital technology can help support this, by identifying these patients more quickly, increasing the available cohort by supporting patients to participate remotely, and by increasing the level and quality of data a single participant can provide.

2. Real World Data (RWD)

While randomised control trials (RCTs) are still viewed as a gold-standard for drug development, real-world data is increasingly growing in its influence on regulators as evidence for drug approval. RWD, which is captured as part of everyday care (for example, in electronic patient records in the NHS), can contain particularly meaningful insight given it reflects the reality of treatment under real-world conditions, as well as the heterogeneity of a patient population often with lots of other conditions.

Advances in artificial intelligence (AI) and analytics, cloud utilisation and computing power have opened up new possibilities for using RWD. Synthetic control arms – an innovative new method that utilises real-world data to form a trial control arm – can significantly reduce the number of patients needed to recruit to a trial, while overcoming the main barrier to recruitment (a patient's fear of being assigned to a placebo).

3. Post-Approval Studies

An important recent trend within clinical trials has been the growth of Post-Approval Studies, which study the effectiveness of a treatment once it has been approved for use. These studies can include thousands of patients and are used to measure the value of a therapy in a real-world setting. The intent is to create evidence of the drug's effectiveness, for instance by showing evidence of a patient's adherence to a therapy and its interaction with other medications a patient may be taking.

These types of trials are also increasingly being mandated by regulatory authorities, who wish to establish the effectiveness and safety of a drug in a non-interventionalist, pragmatic setting and are often imposed as part of the market authorisation of a product. Increasingly, pharmaceutical companies are choosing undertaking these trials as a means of differentiating new therapies from a standard of care by demonstrating increased effectiveness in a real-world setting.

4. Decentralisation

New digital technologies are enabling the decentralisation of clinical trials, enabling part or whole of the trial to be conducted remotely. Notable innovations include:

- Utilising wearable technology or remote monitoring tools to capture patient data and digital endpoints.
- Reducing the need for patients to attend study sites by using video technology to communicate directly with patients.
- Enabling trials to be conducted across multiple jurisdictions, by allowing clinical researchers to work remotely from each other or by recruiting patients further from the investigator site.

5. Clinical research as a care option

Partly due to patient demand for experimentation, and partly due to the changing nature and complexity of medicine, we are seeing increased synergy between clinical care and clinical research, where patients receiving treatment for a condition are signposted to a potential treatment for their condition currently undergoing clinical trials. This provides benefits to both patients and clinical researchers, as patients are given access to potentially effective treatments that would otherwise not be available to them, while clinical researchers are able to more easily recruit patients that meet the needs of the study trial.

For patients who have been given a poor prognosis this type of care can be an attractive option, where approved medicines and therapies are considered either potentially unsuitable or ineffective. However, for clinicians, knowing what therapies are undergoing clinical trials that may support a patient and whether or not a patient is eligible to involved within the trial is often a complex task and this type of care is not as widely offered to patients as it could be. Digital technology can help support both of these trends, helping to join up clinical researchers conducting trials and clinicians who may be caring for patients who could benefit from the research being undertaken.

“The NHS is leading the way with digital apps and digitisation for health care optimisation, with tools like the NHS app and NHS spine. This strength means that the NHS is well positioned to undertake new forms of digital clinical trials. At UKRD, a community of research leaders, we are seeking to build partnerships with technology companies, to help realise the ambition of making the NHS the number one place to carry out clinical research”

Ameet Bakhai, Co-Chair of the UKRD Clinical Working Group and R&D Director at the Royal Free London NHS Trust





How digital technology is transforming clinical trials

The primary benefit of the digitisation of clinical trials is that it can increase and accelerate the number of innovative life-changing therapies coming to market by vastly reducing the time and cost it takes for them to be developed.

It is estimated that it takes on average 10 years with an average cost of \$2.7bn to develop and bring a new drug to market¹⁰. Clinical trials make up the bulk of this time and cost; less than 10% of the drugs that enter clinical trials end up being approved by regulatory agencies.¹¹ When trials fail it is often not because the drug is ineffective among some people in a study, but because it is not effective enough on average across all participants in the intervention arm of a

study – even if even some participants are ‘super-responders’. Where technology can help identify patients whose genetic or phenotypic profile might make them more likely to respond to a therapy, this information can be used to improve cohort recruitment and increase the likelihood of success.

Innovative approaches could make clinical trials more patient-centric by improving trial diversity, improving access and experience for participants, all without compromising data integrity. Digital tools are being utilised to disrupt almost every aspect of a traditional clinical trial, from making it easier for patients to consent to taking part in a trial, to using AI to predict a trial’s feasibility.

“The UK health sector is blessed with a multi-faceted eco-system. To maximise its value, we must strengthen partnerships, while building excitement in being involved in the digitisation of clinical trials and helping patients to lead the way in this new chapter of medicine.”

Sarah Woolnough, CEO Asthma & Lung UK

How digital technology is transforming clinical trials (cont)

Supporting patients to feel confident in their involvement with clinical trials

Digital tools can enable trial information and updates, scheduling and booking for patients, data privacy support and language assistance. They can also enable retention via setting realistic expectations for participants, set rewards and make the consenting process simpler.

Enabling faster and more successful recruitment

Digital tools can enable recruiters to better identify candidates to clinical trials, for example through the use of real-world data, targeted campaigns, and trial matching capabilities.

Care team collaboration

Digital tools enable clinicians to have a unified place where they can document and monitor patient progress. They also support clinicians to share patient trial outcomes with a broader care team appropriately, in a manner which integrates with health delivery - especially in hybrid trials which are integrated into existing care pathways.

Research design, coordination and monitoring to easily derive insights and adjust trial input

Digital tools can enable researchers to optimise a trial design, monitor trial information in real time, proactively support patients to improve retention, and synthesise insights in a regulatory-approved fashion.

Data access and standardisation, to transform data into insight

Unlocking the power of real-world data requires bringing together datasets, curating and normalising data, accessing insights from unstructured data and enabling the use of AI and machine learning (ML).

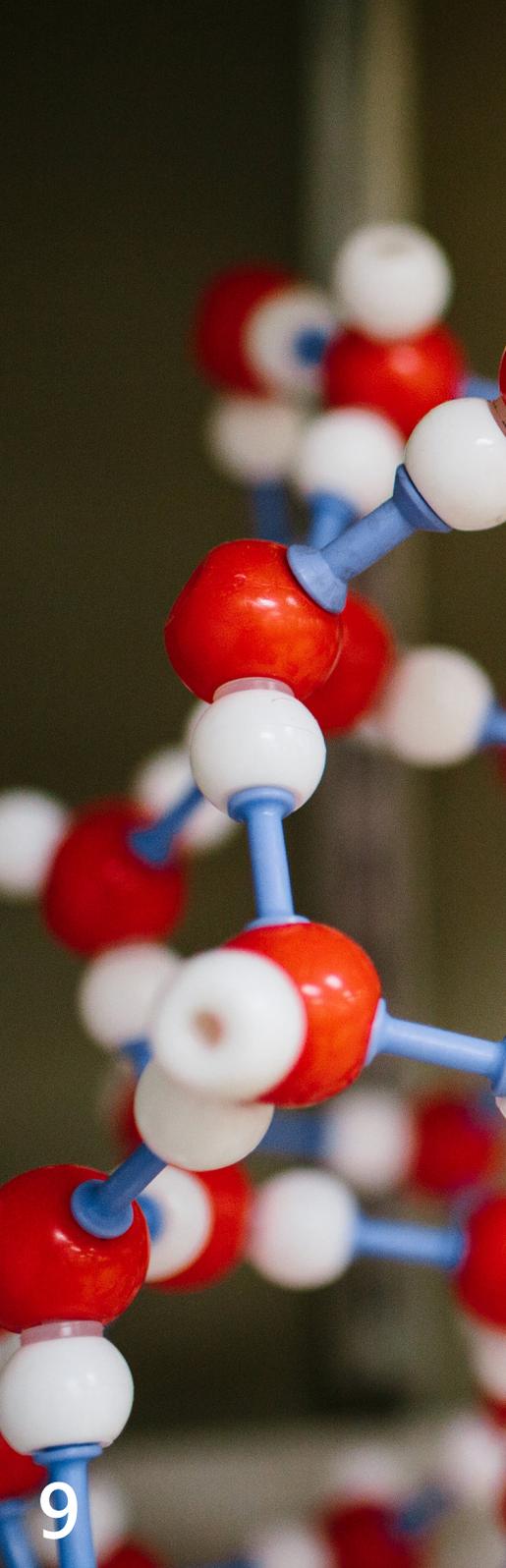
“DTRA has developed in partnership with 140 members 12 initiatives for accelerating the adoption of patient-focussed, decentralised clinical trials, which includes a glossary, a best-practise handbook and improved data connectivity amongst a number of other schemes.”

Amir Kalali, Co-Chair of the Decentralised Trials and Research Alliance (DTRA)





Key challenges



Regulatory

One of the biggest barriers to the adoption of innovative trial methods is the lack of standardised government regulation and compliance standards – and, where it exists, its variability¹². Since many methods for using digital tools in clinical trials are still in their infancy, regulatory standards have not yet caught up with technological capabilities. As a result, more risk averse organisations are unwilling to invest in new technologies, opting instead to continue operating within the current well-defined regulatory-compliant systems.

The lack of regulatory uniformity also creates a challenge for Clinical Research Organisations (CROs), which conduct trials across multiple territories. CROs find it difficult to navigate the various regulatory frameworks, with many choosing not to adopt multi-country clinical trials as the risk exposure is considered too great.¹³

Regulatory bodies have fully recognised and are owning up to this challenge:

- In December 2021, the MHRA released the first of a planned series of guidelines on the use of RWD in support of a regulatory submission for a medicinal product – focused on the assessment of RWD in clinical trial authorisation, and best practice use in clinical trial design.
- The EMA have set out plans for ‘RWE to have been enabled and the value fully established across the spectrum of regulatory use cases’
- The FDA have already codified and successfully embedded three key principles for use of RWE in clinical research in America.

Developing harmonised international regulations for clinical trials is likely to be a challenge for regulators that will take many years. This, however, provides an opportunity for the UK, whose system is viewed as one of the country’s strengths and a key competitive advantage on the international stage.

“The UK, having left the European Union, has the opportunity to design a world-class sovereign regulatory environment for clinical trials that will support the development of innovative medicines and ensure that the UK retains and grows its reputation as world leading base for life sciences, generating opportunities for skilled jobs in the UK.”

Martin O’Kane Deputy Director, Clinical Investigations and Trials Science, Research & Innovation Group, MHRA



Privacy and trust

As clinical trials become decentralised and digital tools are able to capture even more detailed patient data, the risk and consequences of a patient's data finding its way into the hands of a bad actor increases. One way to negate this is to implement stronger governance structures that mandate how a patient's data should be managed and stored.

Given the challenges around developing international protocols for enhanced data privacy during the clinical trial process, technological solutions that promote greater trust through design have a critical role to play. One way to take a step toward this will be through expansion of Trusted Research Environments (TREs), which enable researchers to access secure de-identified health data for research. It is encouraging that NHS England has announced a major investment in TREs in order to support the safe and secure use of data for research purposes.

Of course, TREs are not a panacea and both the Government and industry need to work with patients and the public to build the awareness and understanding of the benefits to society in utilising data for research purposes.'

“Patient and public trust is fundamental. Openness and transparency with patients and the public about clinical research is key to building trust in clinical research and supporting the development of a leading clinical trials sector.”

Matt Westmore, CEO, Health Research Authority

Data reliability and quality

One of the most valuable assets of new DCTs is the data generated from wearable technologies that can help enrich the findings of the clinical trial. However, many of these new data collection methods are in their infancy. Question marks exist over which methods produce reliable results and how best to compare data collected using different methods. There is also a risk of these new technologies having built-in biases that could impact the quality and reliability of the data – for example, some pulse oximeters are less accurate on darker skin tones. It will be important for government and industry to agree accepted methods for analysing wearable data.

Another challenge is in accessing structured, cleansed data. Before health data can be used, it typically requires many iterations of cleansing. Every organisation's data structure is different, and, even within a given organisation – for instance, between different clinical specialities at a trust – the way data is recorded may differ. Important data elements may be found within unstructured notes, using different units of measurement, or differ based on variances between clinical pathways.

A major challenge for organisations that wish to use methods like synthetic control arms is accessing this data and curating it quickly into common data models that can be shared and analysed. Data containing patient information is frequently fragmented across multiple organisations, and linking it across secure environments is a challenge. Many trusts have yet to migrate to fully digital records. Succeeding in doing so will be essential to unlocking the benefits of real world data.

Encouragingly, the need for greater interoperability of IT systems in the NHS is widely understood and the NHS has set aside significant funding to achieve this. The service is currently undergoing significant change, with the introduction of integrated care systems ushering in a new era of collaboration and co-ordination of healthcare in England. Interoperable digital technology is viewed as key to the success of this new era and the clinical trials industry should be a beneficiary of these ongoing changes.

Building public and patient involvement (PPI)

The benefit of patient involvement in clinical trials is widely recognised, with government, industry and patient representatives commending the benefits of deep patient involvement throughout the clinical trial process. These benefits include:

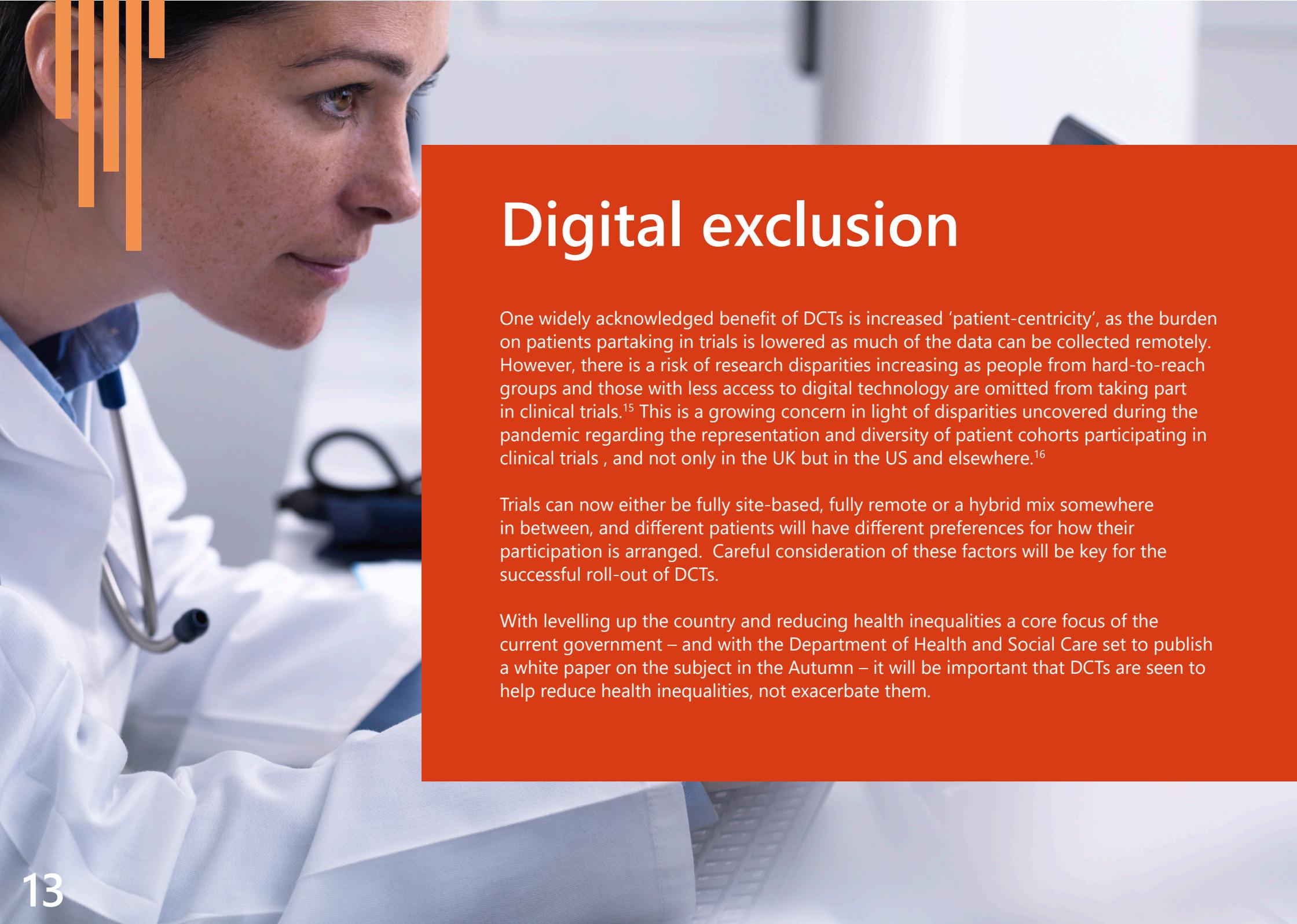
- Ensuring that the study is appropriately designed by helping to define the most relevant research questions to patients.
- Helping to ensure that trial reflects the need of the patient community the research is seeking to support.
- Helping to define a trial design that is acceptable to participants and increases patient retention.
- Improves the process of informed consent and ensures the trial is conducted in an ethical way.
- Improves the communication of findings to participants and the wider public, helping to build trust and awareness of the value of clinical research.

Despite these clear benefits, early and deep public and patient involvement is not happening systematically. While there are many examples of patient involvement done well, there still exists in some quarters a culture that PPI is a tick-box exercise. Challenging and changing this perception is an important step in increasing PPI in clinical trials and the UK is well positioned to do this, with its rich tapestry of patient charity organisations.

“All the evidence shows that when you include patients with lived-experience in the design stage, the research becomes more effective. The UK, with its strong base of charities and patient organisations is well-positioned to take advantage of this and lead the way in building a patient-centric system”

Nicola Perrin, CEO Association of Medical Research Charities





Digital exclusion

One widely acknowledged benefit of DCTs is increased 'patient-centricity', as the burden on patients partaking in trials is lowered as much of the data can be collected remotely. However, there is a risk of research disparities increasing as people from hard-to-reach groups and those with less access to digital technology are omitted from taking part in clinical trials.¹⁵ This is a growing concern in light of disparities uncovered during the pandemic regarding the representation and diversity of patient cohorts participating in clinical trials, and not only in the UK but in the US and elsewhere.¹⁶

Trials can now either be fully site-based, fully remote or a hybrid mix somewhere in between, and different patients will have different preferences for how their participation is arranged. Careful consideration of these factors will be key for the successful roll-out of DCTs.

With levelling up the country and reducing health inequalities a core focus of the current government – and with the Department of Health and Social Care set to publish a white paper on the subject in the Autumn – it will be important that DCTs are seen to help reduce health inequalities, not exacerbate them.

Support for new forms of clinical trials

What is the UK Government doing?

The UK government has made supporting clinical trials a key priority for this administration, part of its wider ambition to make the UK a 'science superpower' and an 'innovation nation'. To support this, the government has announced a significant increase in funding for this area, as well as setting a number of policy objectives.

In March this year, as part of the Government spending review, the Department for Business, Energy and Industrial Strategy announced plans for the UK's largest ever R&D budget¹⁷, allocating £39.8bn for 2022 – 2025. This would support a 33% increase in spending over the current parliament by 2024-2025, with R&D spending increasing by £5bn per annum to £20bn. It is hoped that this will help the Government achieve its aim of ensuring R&D investment reaches 2.4% of GDP by 2027, which will bring it closer to the average R&D spend in the OECD, which is 2.6%.¹⁸

This increase in funding followed the release of a government policy paper in March 2021 called "Saving and Improving Lives: The Future of UK Clinical Research Delivery"¹⁹, which set out the Government's vision for supporting clinical research. The paper set out five key themes that underpin the improvements the Government is seeking to make to become a world leader in clinical research delivery:

- Clinical research delivery embedded in the NHS
- Patient-centred research
- Streamlined, efficient and innovative clinical research
- Research delivery enabled by data and digital tools
- A sustainable and supported research delivery workforce

Following this, in July 2021 the Office for Life Sciences published its long-awaited 'Life Sciences Vision'²⁰, which outlined the Government and life science sector vision for the next decade. The paper set the ambition to "drive value creation for industry and patients, through faster, cheaper, better-quality and more diverse clinical research, delivered through a digitally enabled and pro-innovation clinical research environment".

Following this, in June 2022, the Government published two landmark policy papers for driving a digital revolution in health and social care. The first was the "Data saves lives" policy paper, which set out a plan for capitalising on data utilisation in health and social care, giving patients power over how their data is used and allowing researchers to access data in secure ways to drive innovation and deliver cutting-edge care. The paper committed to creating datasets at scale through a Data for Research and Development Programme, as well as to publish an implementation plan to progress UK priorities for clinical research, as set out in the March 2021 Future of Clinical Research Delivery policy paper.

The second policy paper was the "Plan for Digital Health and Social Care", which is widely considered the most significant policy statement on the digitisation of the NHS and social care for many years. The paper set out in detail how the Government plans to drive a major leap forward in the digitisation of the NHS, and an initial £2 billion from the spending review has been earmarked for this digitisation. While the plan primarily focuses on the improving the care delivered by the NHS, there are likely to be benefits upstream for clinical researchers with the acceleration of the digitisation for the NHS making it a more hospitable place to conduct clinical research.



In order to execute these ambitions, in March 2022 the Government announced the expansion of Trusted Research Environments (TREs) by committing £200m of funding to support NHS-led health research through these privacy-preserving platforms.²¹ These commitments are underpinned by efforts to create an environment for a safer use of data. In April this year, the Government published an independent review²², which was carried out by Professor Ben Goldacre on how to achieve this ambition. Furthermore, NHS England has committed to the creation of a national federated data platform²³, one of the purposes of which will be to enable health research to be carried out at scale across the NHS's data assets.

“If industry, regulators, academia and patient organisations come together to create a success story, then the UK could blaze a trail in the digital clinical trials sector.”

Dan Vahdat, CEO and Founder, HUMA

Imagining the future of clinical trials

What can the future look like for clinical trials?

As the future state brings routine clinical care together with clinical trials, industry is poised to take advantage of the disruptive tech trends which can service the needs of both healthcare and life sciences.

In this vision of the future, patients are automatically identified and matched to trials using AI/ML, and candidate diversity and eligibility is increased through access to real world data. Once enrolled, patients can be given digital access to trial updates, language assistance, as well as scheduling and consent in a user-friendly manner. Their trial may well be conducted remotely, with digital tech enabling the collection of trial endpoints through wearable devices, apps, or remote teleconsultations. For some patients, there may be little to distinguish ongoing care from enrolment into a trial. Such options

reduce the burden on patients and increase flexibility, improving the likelihood of retention.

In the background, clinicians and site coordinators can collaborate on trial progress, proactively monitor patients and address risks, share appropriate information with clinical groups as necessary and use this data to create and amend regulatory filings.

Researchers can begin to design trials which take advantage of these technologies: with increasing access to curated, diverse, high quality real-world data, trials can incorporate synthetic control arms and virtual patients into their design. Centralised monitoring of results can be accomplished from a number of different sites and sources; patients can be stratified to find new insights

and protocols can be reviewed and updated based on risks.

These technologies can also support researchers in designing more efficient trials with a higher likelihood of success. Utilising historical data on trial design, duration, cost and success, researchers are able to gain deep insights in how best to carry out a trial to ensure it achieves a successful outcome.

This future creates a flywheel effect between healthcare and research, with patients at the centre and receiving the benefits of each. Cloud and open-source technologies are leading the way in shaping these technologies, as well as the standards of data privacy and security which enable them, to unlock this vision for clinical trials and for patients.



How Microsoft and its partner ecosystem are supporting this vision of clinical trials

Microsoft has two key capabilities to support our partners in delivering innovative new trials: our Azure Health Data services, and Microsoft's Cloud for Healthcare framework.

Azure Health Data Services

A key area of focus for Microsoft is supporting organisations to realise the potential of real-world data, helping overcome the challenges outlined earlier in the paper. Our Azure Health Data Services team supports data access, integration and standardisation, bringing together data silos to create insights using secure, interoperable standards. Microsoft is a key contributor to the Clinical Data Interchange Standards Consortium (CDISC), helping develop tools which meet the needs of industry in a regulatory-compliant manner. Our data team has created capabilities to help access unstructured data, and make data discoverable (such as metadata cataloguing), paired with secure Trusted Research Environment capabilities. Microsoft is also working with healthcare industry partners on capabilities to support patient identification and recruitment, using natural language processing (NLP) on real-world data, within oncology and other clinical domains.

Microsoft Cloud for Healthcare

The Microsoft Cloud for Healthcare framework accelerates our partner organisations' digital roadmap, enabling them to reimagine each part of the clinical trials process. Microsoft is a member of DTRA (Decentralised Trials and Research Alliance), helping us understand and support the capabilities required to deliver innovative trials. This includes technology-enabled trial designs, hyperselective patient recruitment, and hybrid and remote trial capabilities. This toolkit supports life sciences companies, contract research organisations (CROs), research organisations and digital technology firms enable innovative trials.



Microsoft has a range of partners, from start-up through globally established, providing technologies for innovative trials. Here is a subset of our partners:

EPAM has worked with clients such as Jabil and CRUK (Cancer Research UK) supporting solutions in a safe, transparent and supportive manner. EPAM leverages Microsoft technology to create a patient-centric digital clinical trial experience that connects patients, CROs, and healthcare provider teams.

A reduced reliance on in-person site visits means increased access to patients of greater regional and economic diversity. With less barriers in travel and location, expanded telemedicine means more eligible patients enrol in trials. Recruitment and trial visits to patient homes enrich the overall patient experience.

Tools and resources to monitor patients remotely allow for early interventions and digital support in real-time. This improves patient retention with an increased level of engagement through helpful notifications and medication adherence guidance. Combined efforts between EPAM and Microsoft result in much-needed flexibility, reducing time to market.

ICON plc is a world-leading healthcare intelligence and clinical research organisation. From molecule to medicine, it advances clinical research providing outsourced services to pharmaceutical, biotechnology, medical device and government and public health organisations. ICON has applied its experience to develop its built-for-purpose 3rd generation Digital Platform hosted securely on Microsoft Azure. The ICON Digital Platform (IDP) offers a feature set that includes, eCOA, Telehealth, eConsent, eSource for Home Health and Connected Devices. IDP captures, curates and consumes data from multiple sources to support the operationalization of decentralised clinical trials. IDP leverages Microservices and an API-first architecture to enable configurability and interoperability with clinical trial data. The platform is modular, configurable, scalable and meets compliance and regulatory standards such as 21 CFR Part 11 and GDPR.

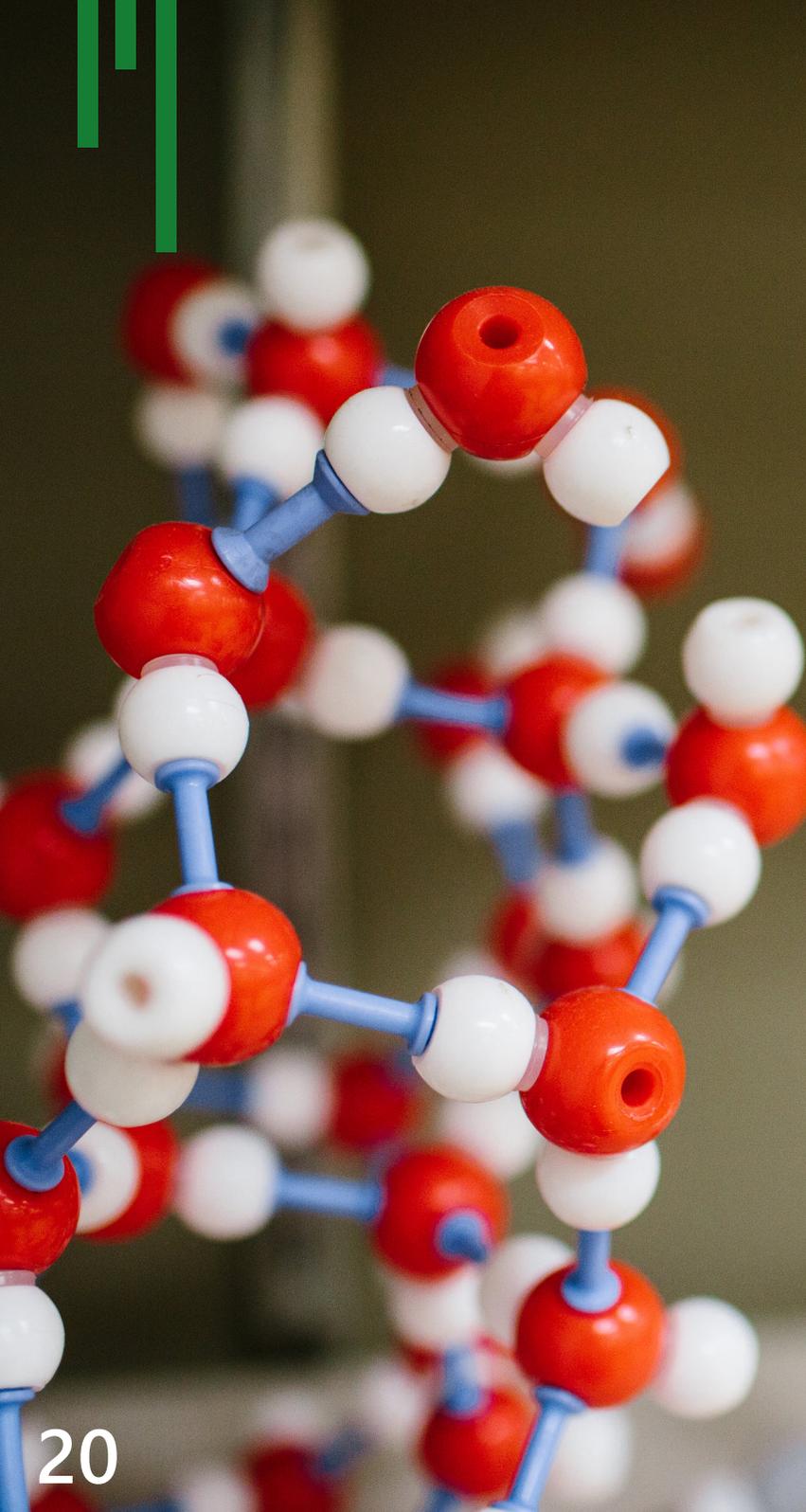
The ICON Digital Platform brings benefits to clinical development by reducing timelines in platform set-up and data integration and has interoperability across systems including EHR, EDC and IRT. The platform leverages access to Mapi Research Trust to enable and support rating scales, quality of life questionnaires, and other validated instruments. Patients caregivers, principle investigators, study coordinators and health nurses are all able to access and provide information to the platform via remote devices and wearables, while the platform provides a central location to collate, analyse and review study data.

Huma has built a highly configurable, disease-agnostic, decentralised and hybrid clinical trials platform that can help improve trial participation, diversity, engagement and efficiency, in multiple languages and regions. Research has shown that the platform can support the speedy recruitment of patients to a trial, increase patient retention and increase adherence to medication. The platform was used to support the largest population-based app study of its kind, collecting 1.6m data points over 10 months for a greater understanding of pre-symptomatic COVID-19 infection. Supported by Microsoft's technology, Huma's platform can help its partners manage multiple sites; screen and onboard participants; obtain informed consent; allow carers and proxies to respond on their behalf; use questionnaires, videos and images to collect data; capture vital and non-vital signs remotely; offer telemedicine and connect to electronic health records and data registries.

Equideum, a ConsenSys partner, builds person-centered healthcare and research networks called Data Integrity and Learning Networks (DILNs), which feature advanced privacy preservation. Equideum's platforms are powered by Ethereum, tokenization, decentralised artificial intelligence (AI), and confidential computing, supported by Microsoft capabilities. The organisation prioritises populations with uniquely complex healthcare needs and the aim is to improve population health and clinical outcomes by impacting access and equity. Equideum is innovating in the field of privacy-preserving clinical trials matching, e-consent, and precision medicine applications.

Pangaea Data uses state-of-the-art artificial intelligence methods to improve outcomes through characterization of patient journeys and disease trajectories by extracting and summarizing clinically validated intelligence from patient data in a federated privacy preserving manner. Patient data includes both structured (discrete values like ICD codes, vital signs) and unstructured textual data (like doctors notes, discharge summaries and family histories). Customers use Pangaea's platform, built on Microsoft technology, for discovering new clinical features to characterize target patient populations, find more undiagnosed, miscoded and at risk patients across diseases, finding genes linked to clinical features in the context of drug or biomarker discovery, recruiting more patients for clinical trials, predicting prognosis and for real-world evidence (RWE) studies.

Faro Health's Azure-based cloud platform helps address the operational problems and delays caused by the traditional word processing and spreadsheet driven method of clinical protocol development. Software assisted design of the Schedule of Activities provides real time insights into performance and quality metrics during the clinical protocol development process. This ensures teams can collaboratively make informed decisions about the impact of every study activity and its associated measurement. Protocol optimization algorithms provide recommendations to assist teams to adopt modern decentralized approaches.



Call to Action: Microsoft's commitment to helping advance UK clinical trials

Microsoft's mission is to empower every person and every organisation on the planet to achieve more. In the UK clinical trials space, we will work with stakeholders to make the UK a **world-leading environment in which to carry out innovative clinical trials.**

We will support the goal of **improving the quality and extent of patient and public involvement** in clinical trials, from design through to follow-up, leveraging existing infrastructure like the NHS App as well as new technologies.

By accelerating the development of our cloud framework, we aim to **enable our partners to bring technologies and products to market which make trials faster, more effective and more efficient.**

We will continue to **make real world data more accessible**, inspiring our customers to participate in "data collaboratives" in which participants share data appropriately and securely to further health research for society's benefit while simultaneously **building patient and citizen trust and agency.**

Ultimately, our goal is to enable better and more equitable health outcomes by **supporting clinicians to deliver innovative and experimental therapies** through both standard of care and as part of clinical research. We will achieve this by helping to provide clinicians, managers, system leaders and other healthcare professionals with **digital services that can guide and improve clinical decision-making**, so that research is firmly embedded across all pathways.

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Matt Westmore, CEO, Health Research Authority

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Dan Vahdat, Founder and CEO, HUMA

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