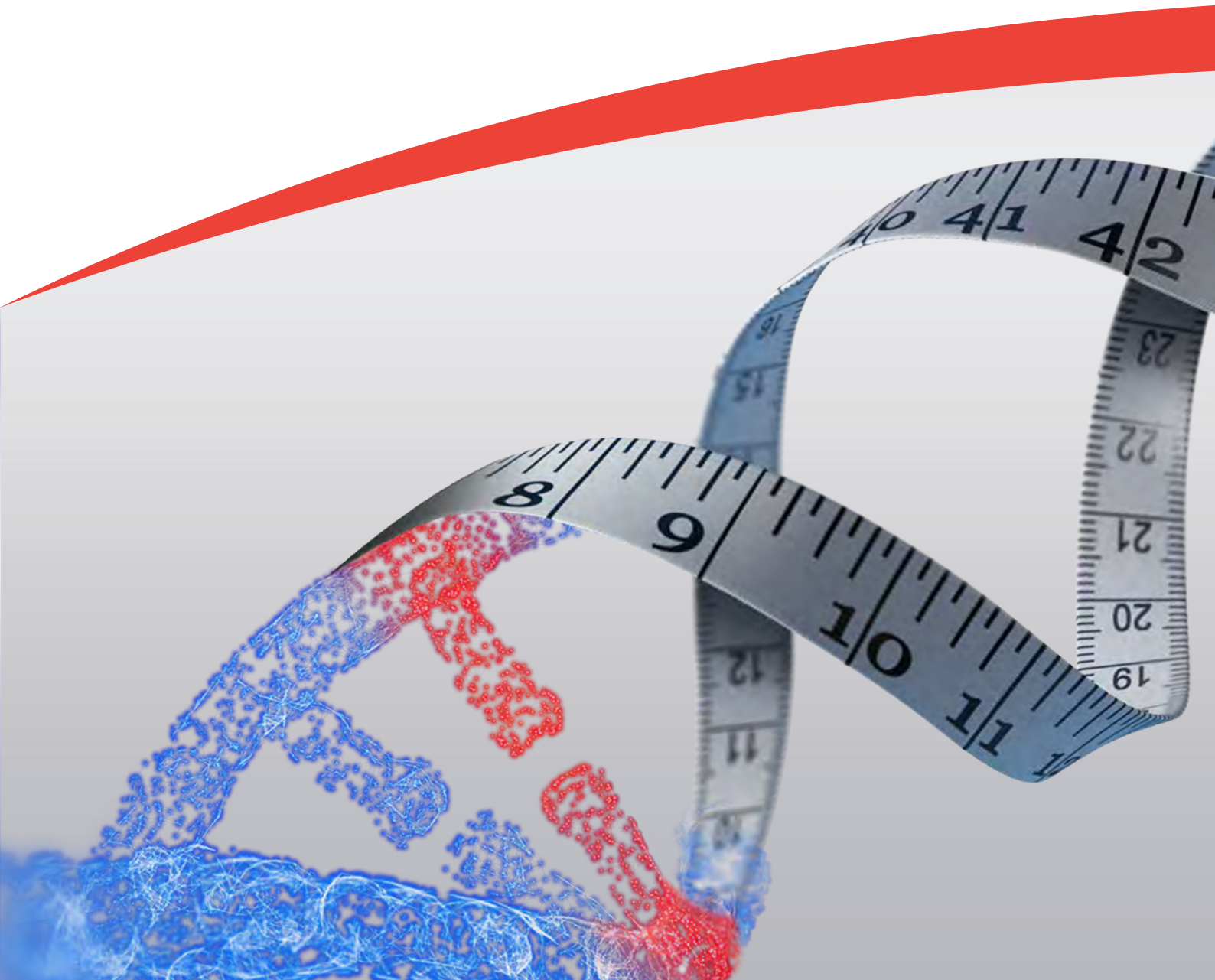
ALMAC

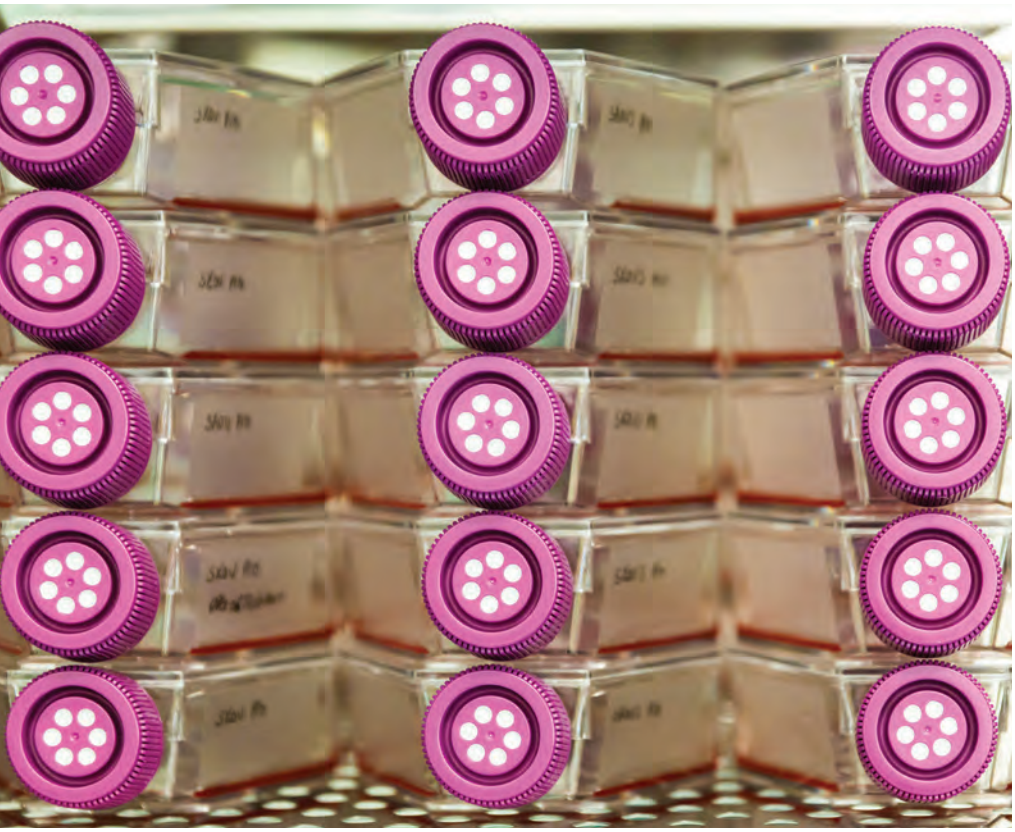
Partnering to Advance Human Health

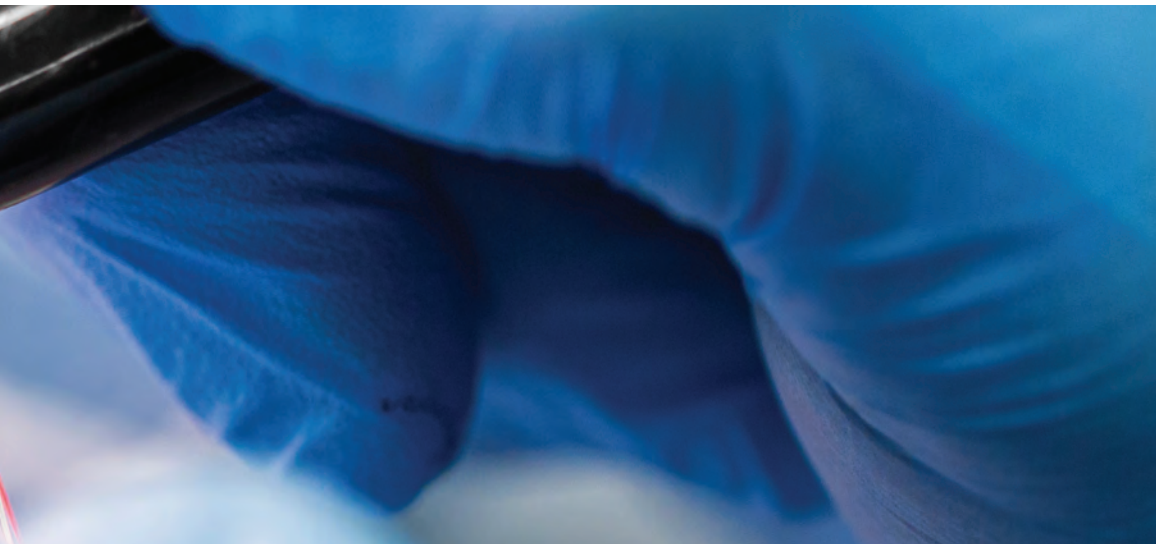
Almac Diagnostic Services

A highly customised CDx partnership approach



Almac Diagnostic Services Customised CDx





Tailored companion diagnostic solutions, utilising complex biology, to help you differentiate your drug in the marketplace.

About Almac Diagnostic Services

Almac Diagnostic Services is a precision medicine company, focused on the discovery, development and commercialisation of complex diagnostic tests. The company, based in Craigavon, UK and Durham, USA has been in existence for over 15 years.

The Almac Diagnostic Services leadership team have worked on many key projects together for over a decade, in partnership with global pharma and biotech clients. Our senior leadership team are also extremely well networked within industry and academia.

As part of the wider Almac Group, we are a stable, privately owned business that is growing globally in line with increased customer demand. Our diagnostic experience spans oncology, immunology, CNS, and infective diseases.

Customised CDx

We know that when it comes to the discovery, development and commercialisation of companion diagnostics for future precision medicines, no two pharmaceutical or biotech companies will ever have the same needs.

At Almac Diagnostic Services, we understand these needs: timelines can be challenging, platform flexibility may be required, regulatory approaches may vary and clinical studies often require bespoke methodologies. Our Customised CDx approach has been designed to offer you an intuitive partnership, with a range of flexible options and specialist supporting services, tailored to your specific drug and companion diagnostic development requirements.

Working with companies worldwide, we create and deliver CDx solutions that are unique - helping you to differentiate your drug in the marketplace.

- Complex Gene Signatures
- Multiple Disease Areas
- Platform Agility
- Global Lab Facilities
- Flexible Commercialisation Models

Our Solutions

We tailor our CDx services to the exact requirements of our clients to ensure their drug and companion diagnostic is competitive in the marketplace.

CDx Development and Commercialisation

We are uniquely placed to partner with clients throughout the entire process of CDx development – from the fundamental research and discovery phase, through the conduct of clinical trials and the manufacturing of test kits or lab developed tests, to patient sample testing.

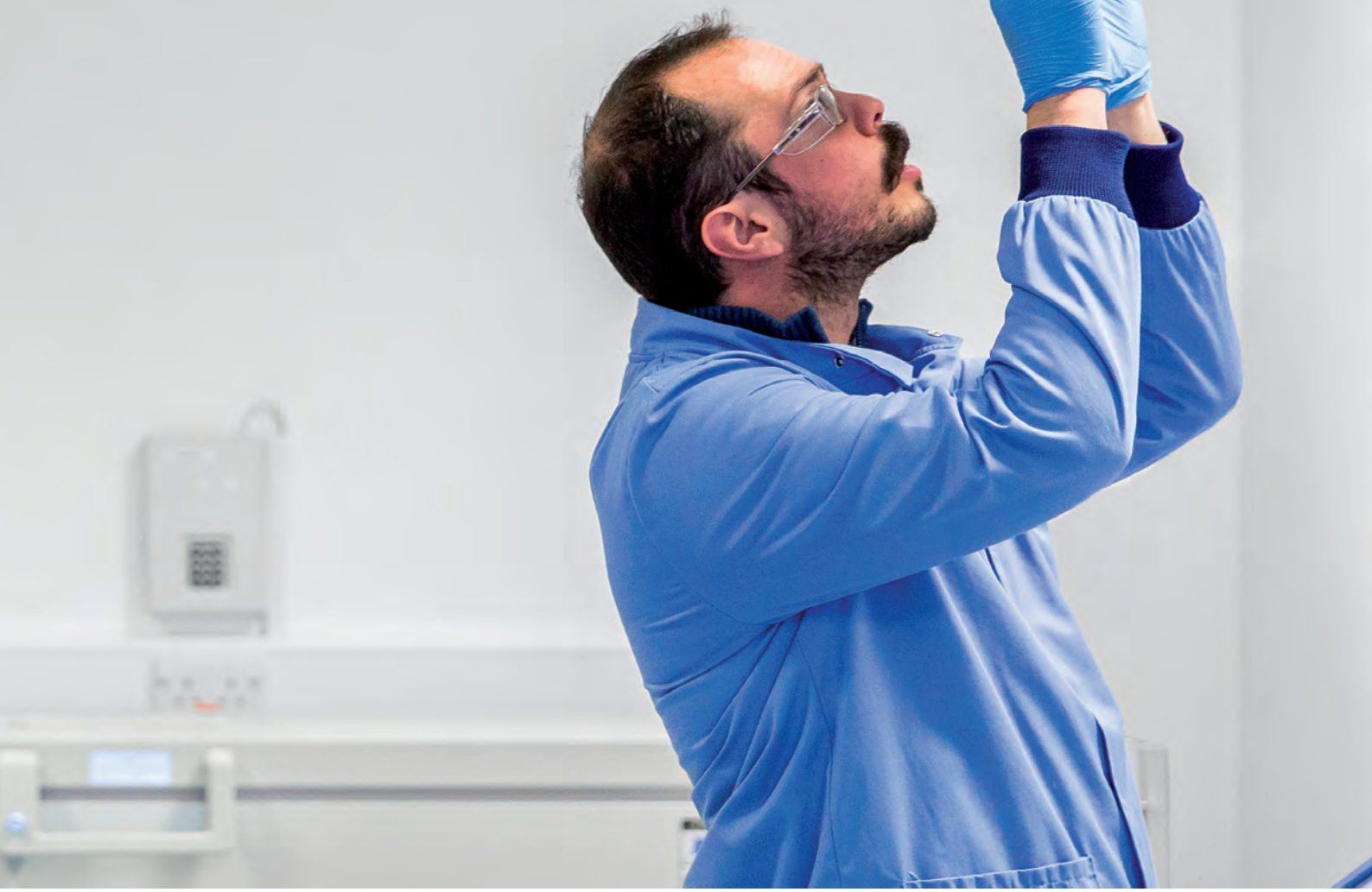
As disease and drug response is a complex process, we fundamentally believe that multiplex gene signatures are the key to developing the precision medicines of the future.

Our experience in using complex biology can be demonstrated through our own internal R&D pipeline of assays across a range of cancer types, as well as our CDx partnerships with existing pharma clients. We have extensive proven experience alongside published and validated results.

Our global, state-of-the-art, CLIA-accredited laboratories deliver both research-use-only (RUO) and clinical diagnostic assays. We also have strong strategic partnerships in place with multiple platform providers, offering clients true flexibility for their CDx requirements. We have the key organisational and logistical resources necessary to provide an end-to-end service, which can be scaled up to support every major market from our clinical laboratory hubs in the USA and Europe and our partnership laboratory in Asia.

With expert supporting services teams in Project Management, Bioinformatics & Biostatistics and Quality & Regulatory Affairs, we ensure that your individual project objectives are met on time, within budget and that deliver customised solutions that add real value.

Services Include: Design Control & Risk Management, Sample Sourcing, Assay Development & Validation, Assay Software Development, Manufacturing, Regulatory Submissions & Registrational Trial Testing.



From left to right; David Porter: Senior Laboratory Scientist, Marie Fox: Laboratory Scientist, Efstratios Efstratiou: Laboratory Scientist

Clinical Trial and RUO Assay Development

We have extensive experience in the development and delivery of multiplex RNA, DNA and Protein based Clinical Trial and RUO assays. We work from multiple tissue types and offer clients platform agility and choice to be able to run their assays on a wide range of platforms including NGS, qPCR, and IHC.

Whether we carry out the biomarker discovery, or Pharma or Biotech clients come to us with biomarkers of their own, we are experts in developing these into tests for clinical delivery.

Services Include: Assay Design & Migration, Platform Selection & Migration, Control Gene Selection, Analytical Validation and Phase I, II and III Clinical Trial Testing.

Clinical Testing

Once the biomarker has been developed into an assay, we offer centralised clinical testing for patient stratification in clinical trials (under CLIA for US based trials and GCP for the rest of the world). We also offer testing on multiple platforms, with the rapid turnaround time required to support the decision making process in trial recruitment.

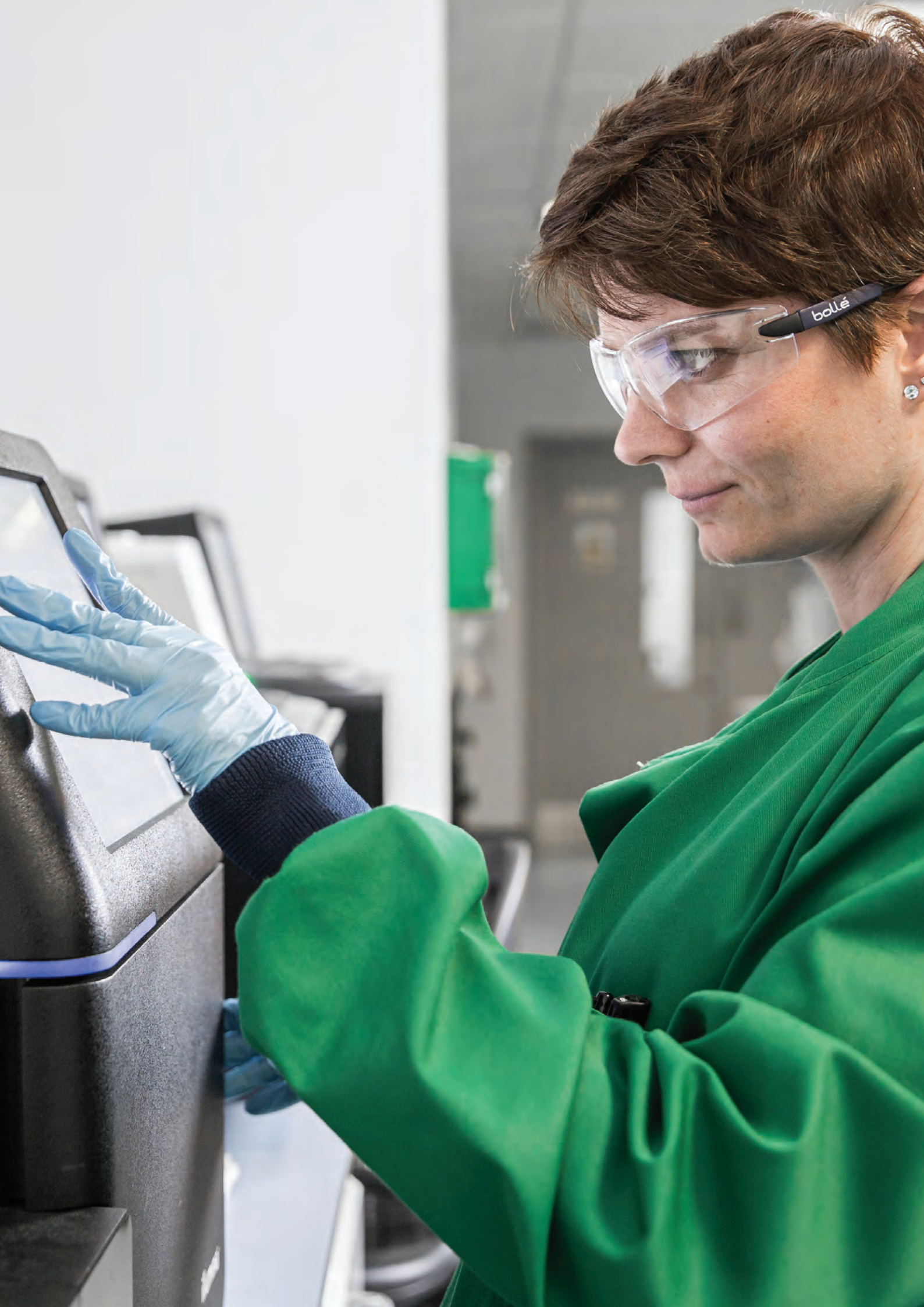
Services Include: Distribution of sample collection kits to clinical sites, Production and control of trial-specific documentation, 24/7 sample receipt, Pathology review, Independent diagnostic confirmation, Multiple testing platforms, Patient test reporting to clinical sites and Regular clinical trial data delivery to sponsors.

Biomarker Discovery

We have extensive experience in the discovery of clinically applicable biomarkers, through our own R&D product portfolio and through developing biomarkers for our partners.

As part of our commercial CDx partnerships, we have discovered signatures that have been brought forward and developed into Research Assays, Clinical Trial Assays, and full Companion Diagnostics.

Services Include: Study Design, Sample Sourcing, Retrospective Sample Collection, Data Generation on Multiple Platforms, Extensive Bioinformatics Support and Proof of Concept Studies.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Our Global Laboratories

Our global state-of-the art laboratories based in Craigavon, UK and Durham NC, USA, alongside our partnership lab in Shanghai, China are ready to deliver both research-use-only and clinical diagnostic assays.

We have fully automated processing in place and a full laboratory information management system, which tracks samples from receipt to the completion of your study.

We already offer clients a wide range of platforms but will adopt additional technologies as required.

Our Range of Platforms

DNA Analysis

- Illumina MiSeq®
- Illumina NextSeq
- Sanger Sequencing
- Nanostring nCounter
- Fluidigm Biomark HD
- Roche LightCycler
- Affymetrix SNP 6.0, DMET, OncoScan

RNA Analysis

- Illumina MiSeq®
- Illumina NextSeq
- Thermo Fisher/Life Technologies Quantstudio Dx
- Roche LightCycler
- Fluidigm BioMark HD
- Nanostring nCounter
- Affymetrix RUO & DX V2 Genechip Systems

Supporting Lab Services

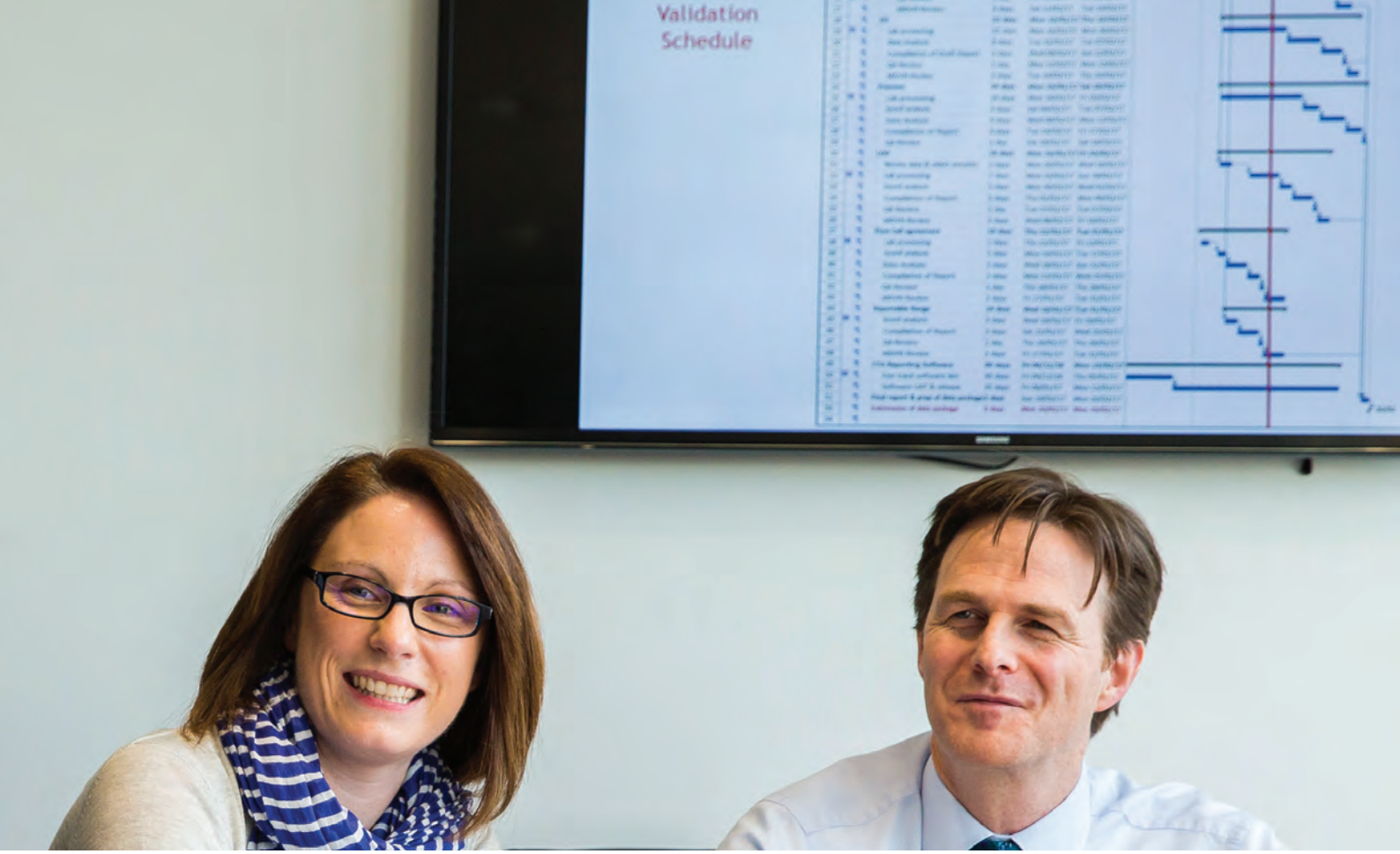
- Pathology
- Sample sourcing
- IHC, ISH, FISH, ELISA
- Tissue pre-processing
- Digital image scanning

"You can make use of any of these services in a fee-for-service manner for routine genomic research."

Maria Comesana-Comesana: Lab Technician

Expert Supporting Services

We aim to become part of our client's extended team, working towards a shared goal of successfully delivering companion diagnostic tests that add real value and assist to differentiate a drug in the marketplace.



From left to right; Emma Brown: Senior Project Manger, Michael O'Neil: Project Coordinator, Jude O'Donnell: Project Group Manager, Peter Kerr: VP of CDx Development

Partnering with Almac Diagnostic Services, you'll have access to extensive bioinformatics, project management and quality & regulatory supporting expertise.

Project Management

We recognise that each biomarker project is unique and has its own challenges. Our Project Management team work with clients throughout their clinical study to provide a comprehensive service from initial study design and planning, all the way through to the commercialisation of a diagnostic test.

Almac Diagnostic Services will establish a dedicated Project Manager as a client's single point of contact to ensure that all key deliverables and timelines are met and that regular communication is provided throughout project. We tailor our service around our client's specific needs and act as a trusted advisor to many of the Pharma and Biotech companies we partner with. We work with them in partnership during the lifetime of the project to adapt to changing requirements if necessary with speed and efficiency.

Quality Assurance

The growing importance of biomarkers in precision medicine means that our RUO and clinical testing laboratories also need to meet the highest standards of quality and safety. Almac Diagnostic Services quality accreditations demonstrate that we meet these standards, providing complete confidence to our clients.

Laboratory Accreditations:

- CLIA (US Clinical Laboratory Improvement Amendments)
- CAP (College of American Pathologists)
- Human Tissue Act UK (HTA License)
- US State Licences: New York (CLEP Permit), Florida, California, Pennsylvania and Maryland

Laboratory QMS:

- We comply with GLP, GCP and GCLP

Laboratory Processing Certifications:

- ISO 15189 and ISO 17025

Manufacturing Certification:

- ISO 13485

Regulatory Affairs

Our regulatory team has significant experience in working with regulatory agencies through our internal diagnostic pipeline as well as with our pharma partners in joint regulatory meetings. We currently manage regulatory plans for companion diagnostic tests in multiple global regions including USA, Canada, Europe, Japan and China.

We have the regulatory expertise required to help pharma and biotech clients navigate the regulatory landscape in key global territories. We currently have over 30 regulatory staff in total, of which 10 directly work in Multiplex CDx development.

We provide regulatory support solutions including: Global regulatory strategies for CDx development, CDx and IVD pre-submissions, IDE submissions, EU device & performance evaluation registration, Device classification assistance, Analytical and clinical protocol design, Regulatory submissions, Regulatory agency liaison, Medical device reporting and Post-market support.

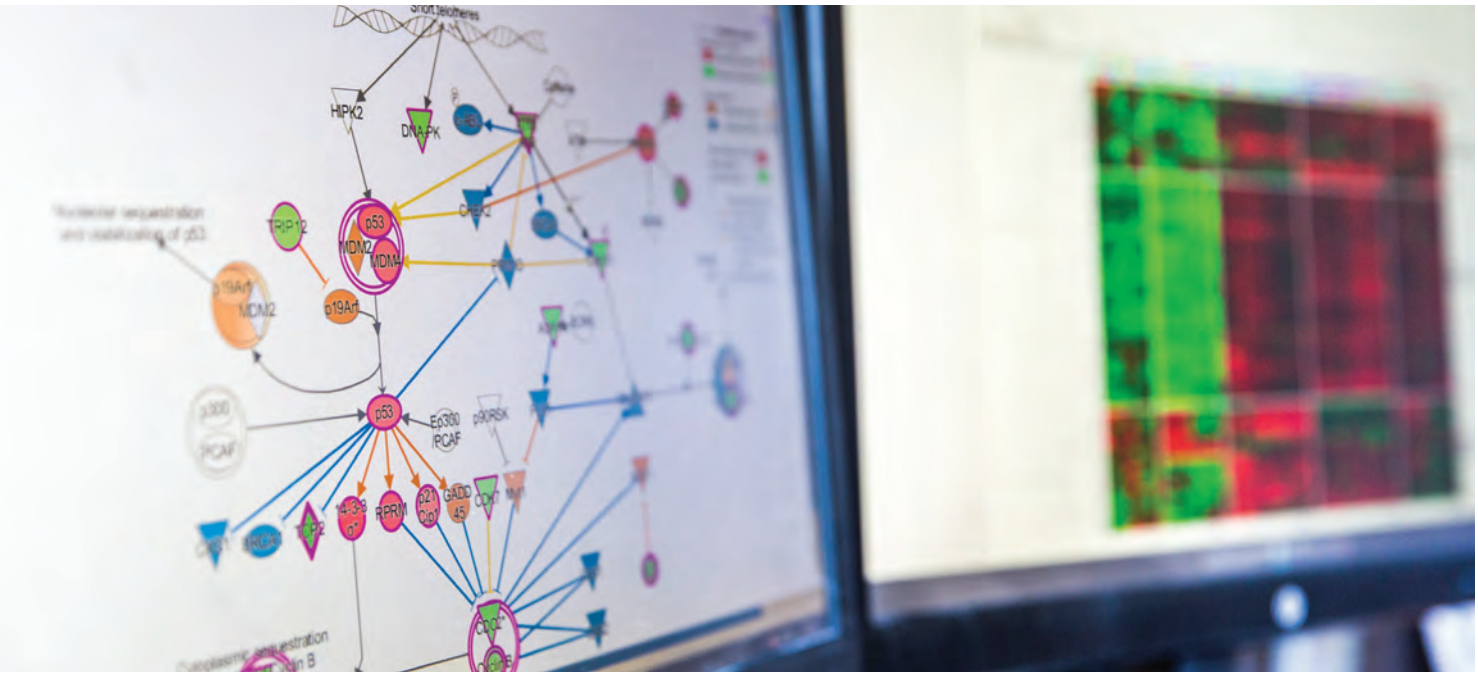
Bioinformatics and Biostatistics

Our expert Bioinformatics and Biostatistics team partner with clients throughout their clinical study, fully supporting the discovery, development and delivery of biomarkers.

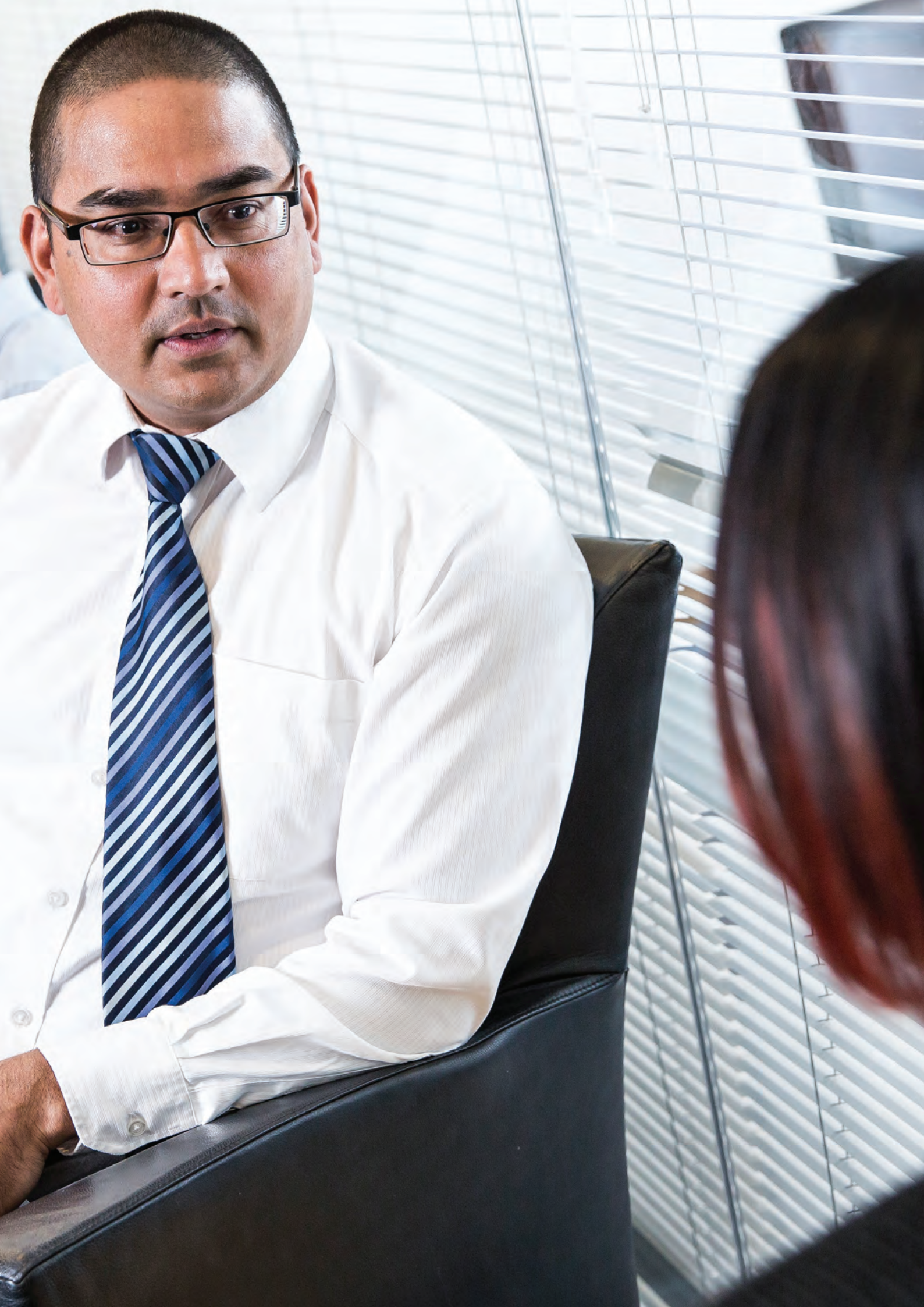
Recognising that our customers' needs are unique, we have also developed numerous customised solutions and workflows. These solutions range from novel scripts and analysis pipelines to fully developed in-house software packages.

With a team across three regions in the UK, EU and USA, our highly experienced scientific experts have a substantial understanding of bioinformatics software development, data management, machine learning, statistics and biostatistics, molecular and cell biology, drug discovery & development and diagnostic product development.

Supporting them, we have an integrated technology infrastructure designed to process and analyse large data sets quickly and securely.



Neeraj Mehta: Design Control and Risk Manager



Interested in a customised CDx partnership?

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