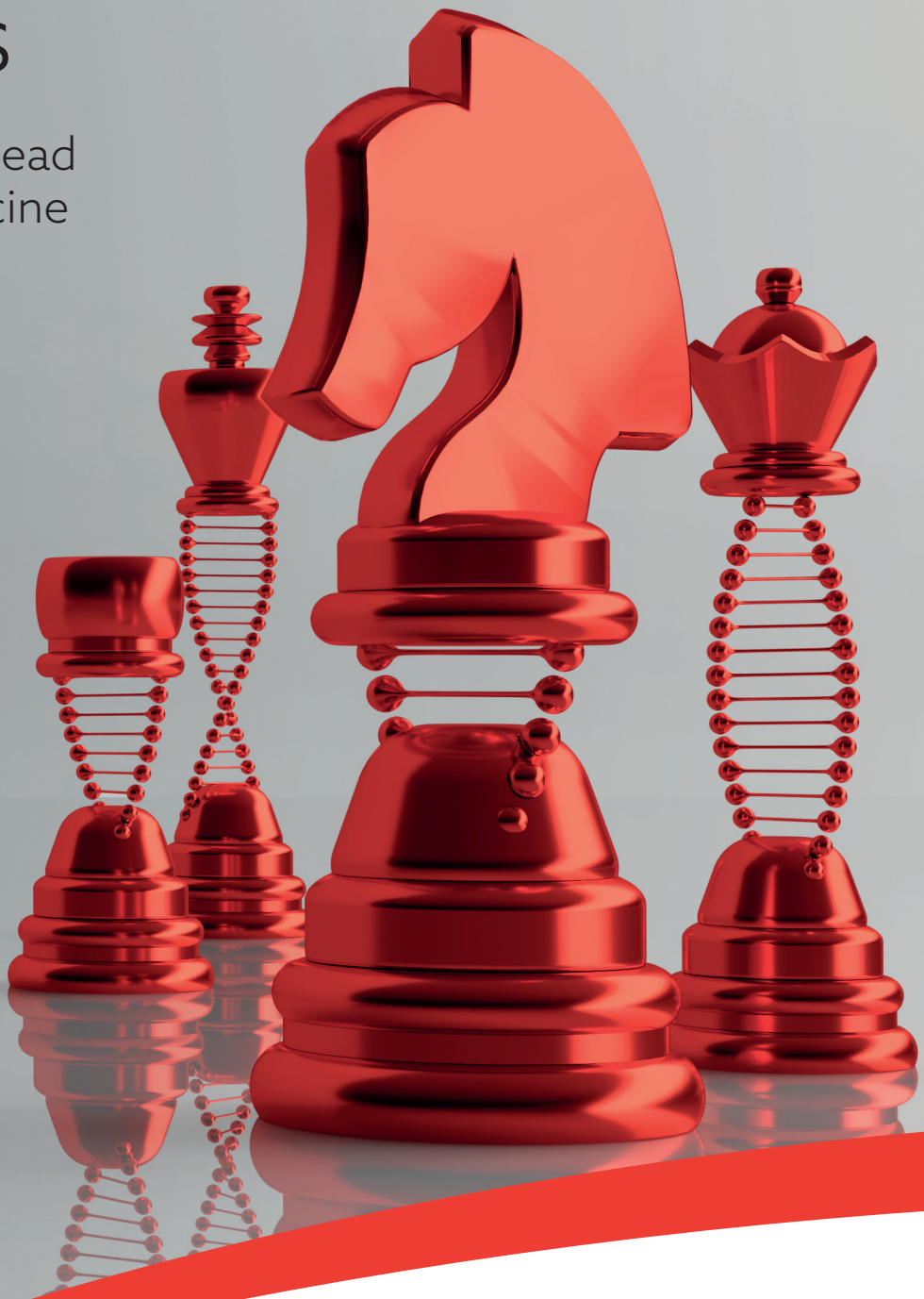
ALMAC

Partnering to Advance Human Health

Almac Diagnostic Services

Always a move ahead in precision medicine



Almac Diagnostic Services

Your global partner for biomarker discovery, development & commercialisation

About Us

We support global pharma and biotech companies with their biomarker strategies from discovery through to companion diagnostic partnerships. We have clinical and research laboratories in Europe and the USA, alongside strategic partnerships in China, enabling us to support global studies.

The services we offer fall into three main categories:

- **Genomic Services**
- **Clinical Trial Assays**
- **Companion Diagnostics**

Why Almac

Almac offers a unique business model to our clients, providing **complete flexibility** to support the strategies required to deliver precision medicine. We offer a range of platform and chemistry options, across many different sample types and disease indications so you are not tied to one solution and will always have the freedom to move. We also have a range of **innovative** proprietary biomarker discovery software reporting solutions that our partners can access to support novel analysis of their data.

We enable our partners to rapidly take their drug and biomarker into clinical trials whilst supporting an evolving programme with expert advice and guidance along the way.

Commercially, we can support single site and IVD kit companion diagnostic development. We are also flexible on the downstream commercialisation strategy where we can manufacture and market your assay, or we can support the transition of the CDx to an alternative commercial company.

Almac Diagnostic Services has highly experienced teams (Scientific, Regulatory, Data Sciences, Medical and Commercial), with a **reputation for quality** and a highly collaborative approach.

We will become an extension of your team, who you can **trust** to ensure the success of your project.

Quality & Compliance

Almac Diagnostic Services' laboratories meet the highest standards of quality and safety.

Accreditations

- CLIA
- CAP
- UKAS to ISO17025
- UKAS to ISO15189

Permits, Licences & Regulations

US State Licences:
- New York (CLEP Permit)
- California
- Pennsylvania
- Maryland
- Rhode Island

Human Tissue Act UK:
- HTA Licence

Compliant with the principles of:
- GCP
- GCLP

Certifications

- EN ISO 13485:2016
  (For design development and manufacturing on in vitro diagnostic nucleic acid technique based assays for gene mutation and expression analysis)
- ISO14971
- IEC62304
- GLP

Our Services

Genomic Services

Almac offers a range of Genomic Services from multiple platforms, generating high quality data from DNA and RNA for clients, alongside proprietary bioinformatics pipelines to aid novel biomarker discovery.

Range of Platforms
We offer the flexibility of a range of platforms and chemistries for clients to choose from with experience in analysing many different sample types.

Data Analysis Solutions
Almac has the bioinformatics, biostatistics and software development expertise to provide unique approaches to analysing large data sets and uncover new insights.

For RNA – Almac clara^{T} gene expression report. For DNA - Almac WES Software Suite & Almac Genomic Variant Report.

Sample Management Service
Almac offers a full range of sample management services including sample sourcing, receipt and accessioning, sample preparation & QC, LIMS reporting, storage, logistics and downstream processing capabilities. We can generate high quality, annotated digital images for clients and have a team of consultant pathologists who can remotely conduct digital pathology review.

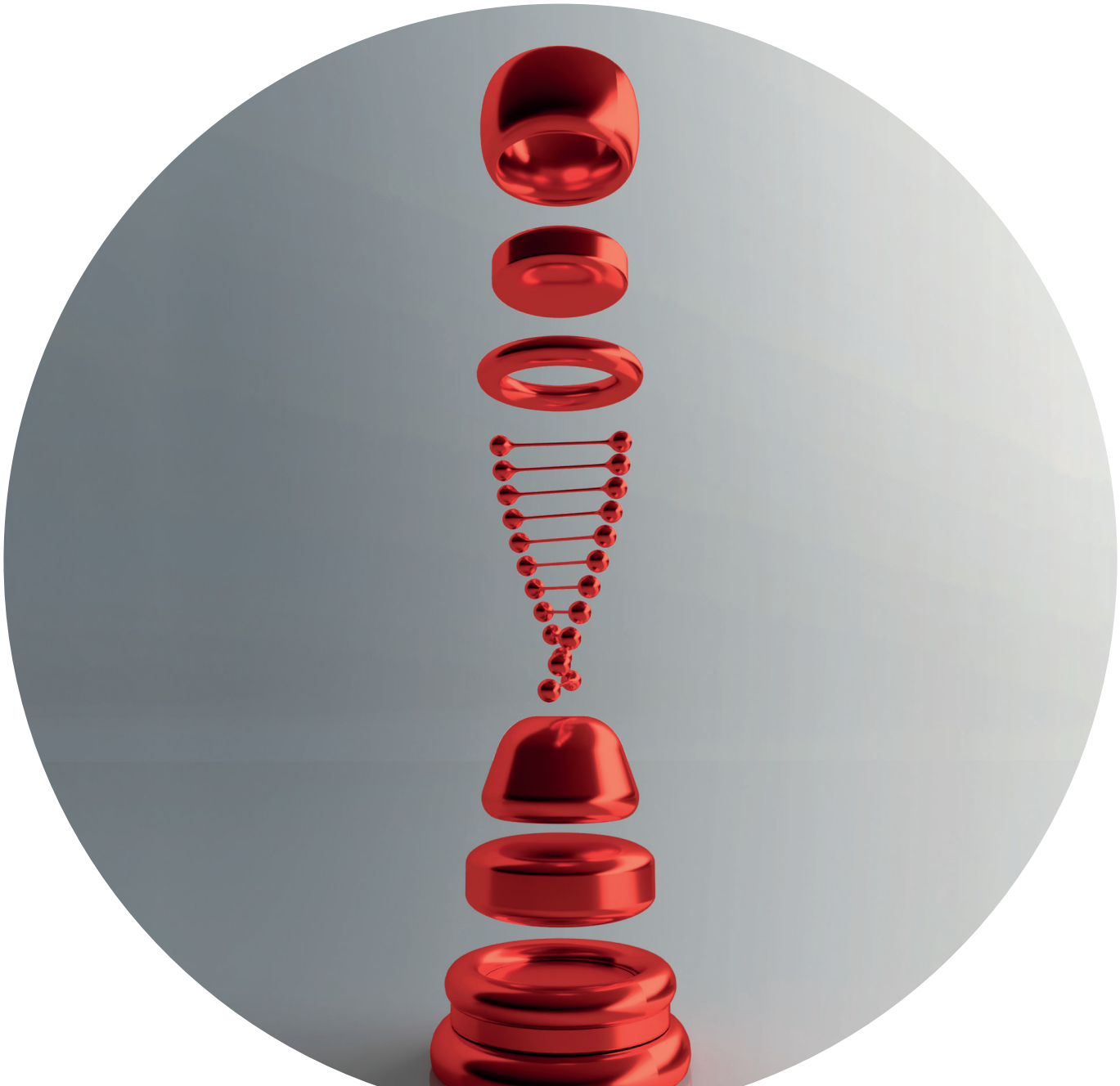
Clinical Trial Assays

Almac offers a comprehensive Clinical Trial Assay development, validation & delivery service with a range of flexible options across multiple technologies.

Clinical Trial Assay Development & Validation
We have extensive experience in working with global biopharmaceutical companies on RUO and IUO Clinical Trial Assays and can advise on the most suitable platform and chemistry options to meet project goals. We typically consult early on future commercialisation needs to minimise any disruption along the development pathway towards a companion diagnostic.

Global Clinical Trial Testing Solutions
Almac Diagnostic Services offers clinical trial set up, clinical test delivery & clinical trial management from global clinical testing labs in the UK, USA and partnership labs in China. We provide a quality driven clinical testing service managed by a dedicated multidisciplinary team.

Our combined clinical trial testing solution includes Clinical Testing, Sample Collection Kit Design & Manufacturing Service & Sample Management Service. We can provide clients with an end-to-end solution that eliminates the need to outsource to multiple vendors, helping to minimise risks and maximises success for clinical trials.



Companion Diagnostics

Almac offers a collaborative Companion Diagnostic (CDx) partnership approach with a deep understanding of client needs: timelines can be challenging, platform flexibility may be required, regulatory approaches may vary & clinical studies often require bespoke methodologies.

CDx Development & Validation
We are uniquely placed to partner with clients throughout the entire process of CDx development. From the fundamental research and discovery phase, to development and validation, conducting clinical trials and the manufacturing of test kits or lab developed tests, to patient sample testing. With expert supporting services teams in Design Control, Project Management, Data Sciences and Quality & Regulatory Affairs we ensure that your individual programme objectives are met on time, within budget and to high quality standards.

CDx Manufacturing
Our dedicated IVD manufacturing team & processes follow Good Manufacturing Practice (cGMP), are CFR 820 compliant and have achieved ISO13485:2016 certification. These processes ensure consistent assay component supply, adequate reagent / kit release processes for analytical validation studies and ensure a robust assay assembly, labelling, release and monitoring process for final commercialisation.

CDx Commercialisation
Almac Group has over 50 years of manufacturing and global distribution experience to support your CDx commercialisation needs.

Almac Diagnostic Services' commercialisation team will partner early with your commercial team to ensure your assay will be suitable for the target market. Our teams agree a joint commercialisation plan and work in partnership throughout the lifecycle of the product.

We can offer multiple flexible CDx commercialisation models for clients to choose from: Single Site Model, IVD Kit Model or IVD Kit Hybrid model (with bridging).

Supporting Services

Project Management
Our experienced Project Management team work with clients throughout the lifecycle of their project to provide a comprehensive service from initial study design and planning, all the way through to the commercialisation of a diagnostic test. We recognise that each biomarker project is unique and has its own challenges. Almac establishes 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 updates are provided. We foster a collaborative working partnership with our clients through transparency and flexibility to achieve shared goals. Our project managers often become a trusted and valued extension to our client's team.

Data Sciences
Our Data Sciences' team partners with clients throughout their biomarker programmes, fully supporting the discovery, development and delivery of biomarkers. The team has developed novel and proprietary software pipelines for comprehensive DNA and RNA analysis and have a substantial understanding of bioinformatics, biostatistics, data management and software development for diagnostics.

Regulatory Affairs
Our Regulatory Affairs team has significant expertise, built up over many years, to help pharma and biotech clients navigate the regulatory landscape in key global territories. Almac currently manages regulatory plans for companion diagnostic tests in multiple global regions including USA, Canada, Europe, Japan and China.

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.

Clinical Support
Our dedicated Clinical Support team is headed up by Almac's experienced lab directors who are qualified to deliver assays internationally. The team provides medical support for the design, set up and delivery phases of clinical trials. We also offer commercialisation support activities for CDx programmes including medical affairs planning for commercial launch. Almac's medical team has appointed and managed several Scientific Advisory Boards with Key Opinion Leaders and have engaged with Patient Advocacy Groups and Co-Operative Groups to inform product development and meet market requirements.

Contact Us

Make the winning move today

www.almacgroup.com/diagnostics

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