ALMAC

Partnering to Advance Human Health

Biomarkers for Biotech

Maximise Your Drug's Potential

Biomarkers for Biotech

Almac Diagnostic Services 'Biomarkers for Biotech' is a package of solutions tailored to meet the specific needs of the biotech industry.

Almac has built up significant experience, over two decades working with Biotech companies, and have the right skills and global expertise to help you solve your most complex biomarker challenges.

We can help streamline your diagnostic activities, whilst helping you avoid potentially costly roadblocks along the way, ensuring the most cost-effective solution for your biomarker programme.

Almac will partner with you to maximise your drug's potential. We can:

- **Help you to identify & navigate diagnostic pathway options in support of your drug development strategy.**
  - Optimal biomarker assay development and validation strategy to maintain patient safety and data integrity within your clinical trials.
- **Increase your drug's value.**
  - Ensure biomarker-based patient selection within your clinical trials is fully compliant with all local and international regulatory requirements.
  - Modular FDA submission process demonstrating that the companion diagnostic product is on the correct regulatory approval pathway, thereby enhancing your ability to secure further VC investment or future out licencing of drug to large global Pharma partners.
- **Improve your drugs chances of success.**
  - Improve drug efficacy by accurately targeting the appropriate patient population for inclusion in your clinical trials.
  - Rapid diagnostic test results to maintain patient enrolment targets.

The importance of Biomarkers

In today's era of precision medicine, the discovery and validation of biomarkers and their development into clinical tests is critical. Biomarkers have wide ranging applications in drug development, from identifying the correct biological dose to selection of patients for therapy.

The use of biomarkers can add substantial value to a compound in development and the ability to identify those patients most likely to respond to a therapy greatly increases the chances of success for multiple end goals within your drug development programme.

Why Almac?

Almac offers a unique business model to biotech clients, providing complete flexibility to support the biomarker strategies required to deliver precision medicine so that you are not tied to one solution and will always have the freedom to change.

Almac offer:

- **Flexible Business Model** – Fee for Service
- **Range of platform & chemistry options**
- **Multiple disease indications**
- **Multiple sample types**
- **Global Labs** cover **UK, Europe, USA & APAC**

In addition, Almac Diagnostic Services has developed innovative solutions for data generation & analysis utilising Almac optimised workflows, proprietary bioinformatics pipelines & unique reporting tools. One such tool is Almac's claraT, a software solution for novel biomarker discovery from complex cancer RNA gene expression data, covering all 10 Hallmarks of Cancer.

Biomarker Discovery

Almac can help you discover a biomarker or further develop your existing biomarker.

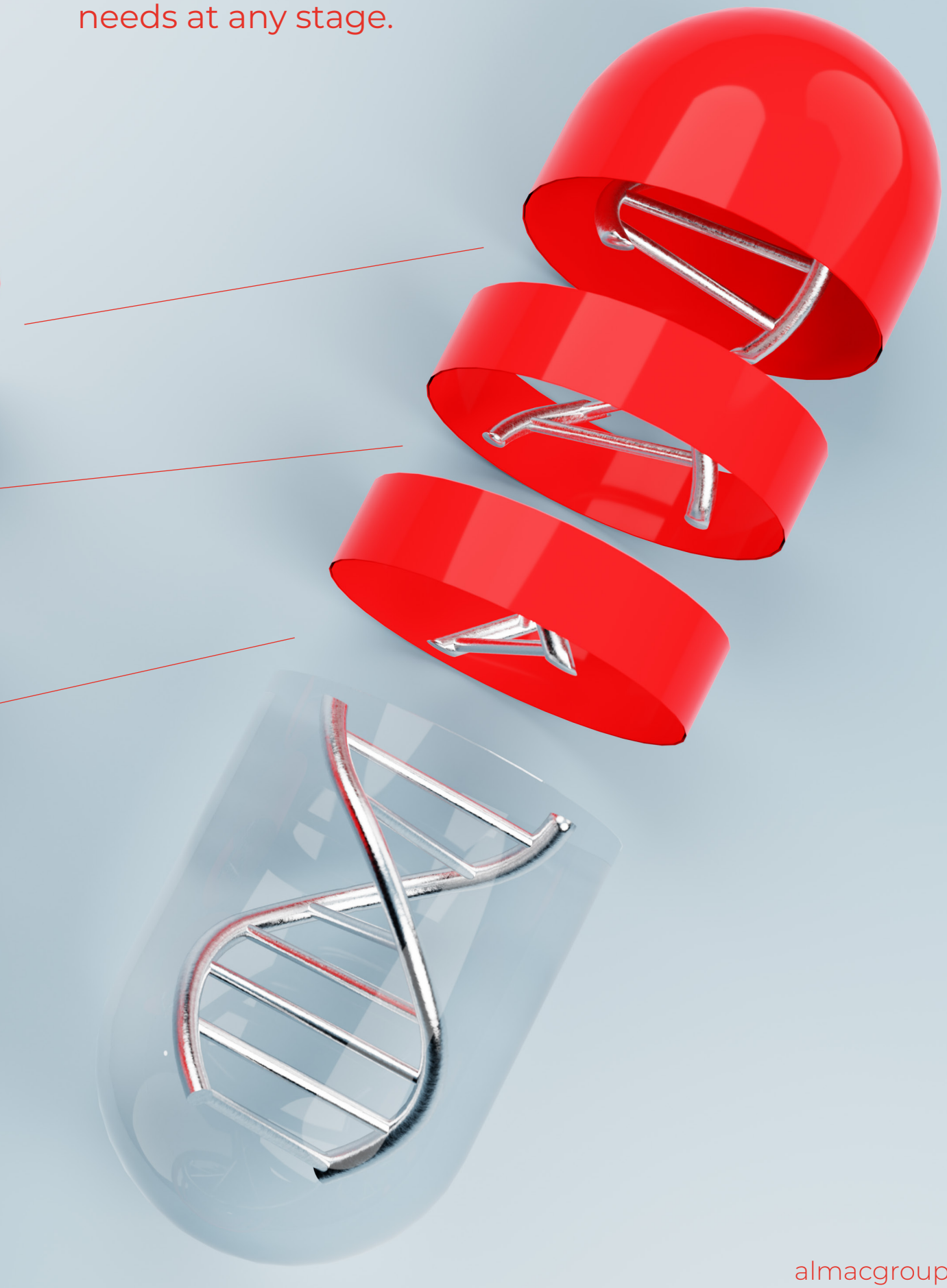
Clinical Trials

Almac can help you develop a robust assay for early phase trial enrichment and assist you with your clinical trial setup and site management.

Companion Diagnostics

Almac can help support the development and approval of your CDx.

We can support your diagnostic needs at any stage.



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Our Core Services

Our global CLIA and CAP accredited laboratories cover UK, Europe, USA and APAC regions.

Our cores services include:

Genomic Services
The flexibility of a range of genomics platform and chemistry options, alongside expert data sciences support & a full sample management service.

Clinical Trial Assays
Comprehensive Clinical Trial Assay (CTA) development, validation & delivery service for research and clinical use assays, alongside global clinical trial testing capabilities.

Companion Diagnostics
A collaborative end to end Companion Diagnostic (CDx) development, manufacture & commercialisation service with the organisational and logistical resources necessary to launch tests in every major market.

Consultancy

We offer a comprehensive consultancy service for biotech clients to help guide your precision medicine studies, whatever stage of the drug development journey you are at. These services can be offered as part of an overall product development package agreement or as a standalone consultancy agreement.

Our consultancy service includes:

Bioinformatics
Bioinformatics is a critical component and often a primary bottleneck in biomarker discovery and validation. Almac Diagnostic Services offers a bespoke bioinformatics consultancy service which can guide your biomarker studies from study planning right through to final analysis and delivery of a validated biomarker.

Biostatistics
Our Biostatistics team offer a rare combination of statistical and genetic expertise, providing clients with optimal strategies and solutions in the molecular diagnostics field. Much more than a traditional group of analysts, our biostatistics team help ensure that the assay meets client's exact customised needs, that studies are designed to ensure success while minimising cost, and that the right analyses will be chosen to facilitate appropriate characterisation of the assay.

Software Development
Our software solutions team has expertise in automation of data processing, instrument integrations, analytical run validity verification, quality control assessments and facilitating patient test reporting. Working closely with clients to identify and refine key requirements at an early stage using a risk based approach to tailor robust solution to meet their exact needs, whether this is biomarker software for testing under CLIA lab regulations, CTA or CDx. All development and validation work is performed with strict adherence to latest regulatory standards.

Almac has extensive experience developing software solutions for RNA and DNA based qPCR and NGS assays. We also have considerable experience developing integrations with cloud platforms and other remote systems using APIs.

Regulatory Support
Almac Diagnostic Services regulatory affairs team has extensive experience in engaging with global regulatory authorities such as US (FDA), EU (MHRA). In addition, we can help you engage with China (NMPA) through our local Chinese agent. We can guide you throughout the Clinical Trial Assay (CTA) and Companion Diagnostic (CDx) lifecycle, drawing on an in-depth knowledge of molecular diagnostic product development. We provide invaluable support to our clients from the investigational clinical trial phase through to the post-market phase, resulting in successful regulatory submissions and ultimately a fast and efficient path to market.

IVDR – Almac can also give Biotech clients up to date guidance and support for your biomarker programmes around IVDR and compliance with the new regulations for Europe.

Partner With Us

Almac is your global partner for biomarker discovery, development & commercialisation.
Interested in partnering with us?

almacgroup.com

Get in touch

UK
diagnostics@almacgroup.com
+44 28 3833 7575

US
diagnostics@almacgroup.com
+1 (919) 479 8850

To start a conversation visit:
almacgroup.com/diagnostics/biomarkersforbiotech