ASTRUM INSIGHTS

Getting **Phase I trials** right first time

How to ensure your Phase I trials comply with quality and regulatory expectations, long-term

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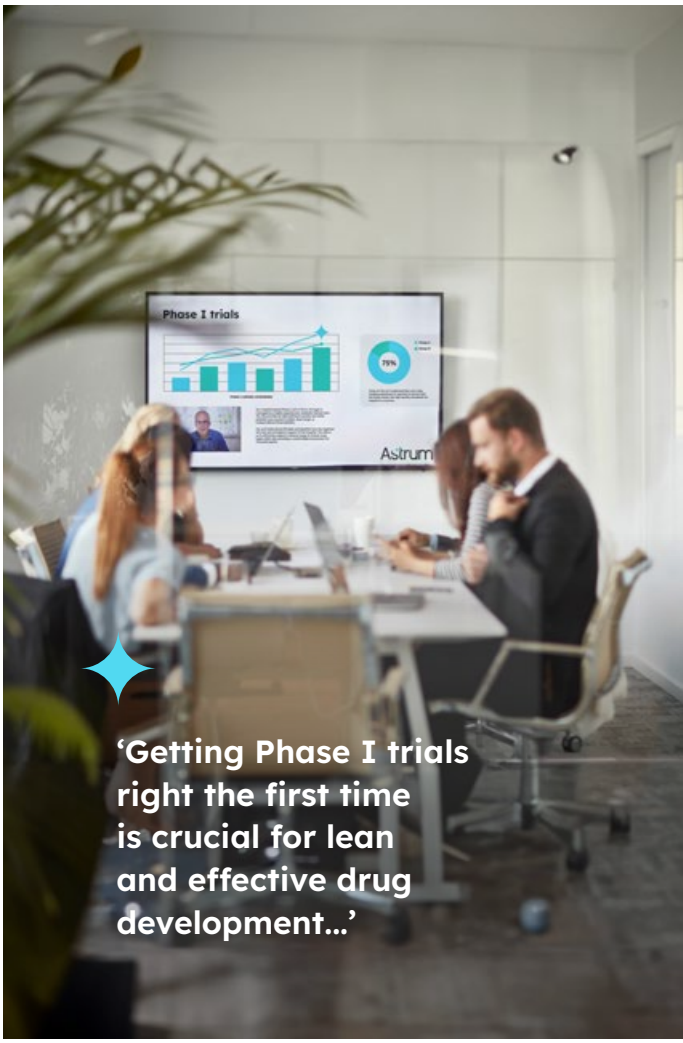
Astrum

Quality of clinical data, competitive timelines, and cost-effectiveness

These are just some of the numerous considerations that Biopharma and MedTech companies need to think about when conducting clinical studies.

Creating high-quality clinical data facilitates good clinical development decision-making, enhances the quality of a drug Marketing Authorization Application (MAA) dossier, and mitigates long-term regulatory vulnerabilities. Shortcomings in the clinical data that support MAA dossiers can potentially result in unreliable outcomes, sometimes leading to entire clinical studies needing to be redone.



Mitigating risk in Phase I trials

Phase I clinical trials are especially susceptible to these outcomes due to their short-term duration. Deficiencies in the clinical trial that result in poor quality clinical data can jeopardise the integrity of the entire MAA dossier. Choosing a clinical site and a CRO with an excellent track record of audits and a commitment to maintaining the highest standards to achieve data quality is not just a strategic decision, but a safeguard against setbacks in clinical development.

Getting Phase I trials right the first time is crucial for lean and effective drug development. This approach prevents the doubling of costs, (both opportunity and financial), and equally importantly avoids the duplication of drug exposure for study participants.

Staying up-to-date with the latest clinical standards

Being informed of the latest standards is paramount for all stakeholders in clinical research, including Sponsors and CROs. It requires a continuous commitment, while always monitoring the most advanced scientific developments. Keeping pace with these can be resource-intensive, and this is exemplified by the US FDA Study data Technical Conformance Guide. This is a document that provides specifications and recommendations on how to submit standardised study data as per the agency

requirements, which was updated in 2023 on six different occasions and impacted operations across various organisations. Understanding these changes ensures compliance with regulatory expectations, and better positions organisations to generate high-quality clinical data. This creates the best possible foundation for successful research outcomes.

Prioritising excellence in Phase I trials and staying current with evolving standards is integral to efficient drug development. By embracing these practices, stakeholders can mitigate costs, enhance data quality, and position themselves for success across the clinical research landscape.

BlueClinical – An Astrum Company, has a comprehensive understanding of the critical requirements for conducting successful Phase I trials:

Phase I experience – with more than 200 Phase I clinical studies performed in the last 10 years in various therapeutic areas, types of dosage forms, and study designs.

Compliance with the latest Clinical Quality Standards – 100% acceptance of MAA dossiers with studies performed at BlueClinical, including review by the US FDA and EMA authorities; acceptance in less than 12 months with no questions raised regarding BlueClinical's study data.

Experienced Staff – A highly qualified and dedicated team. Key staff members have more than two decades of experience.

Inspection clean sheet – audited by more than 70 clients across the world and inspected by INFARMED, I.P. (an EMA representative) in 2014, 2016, and 2021, by US FDA in 2017, and 2019 with no findings ("NAI – No Action Indicated"), and by GCC in 2023.

Regulatory experience – more than 30 clinical studies approved since the CTIS implementation, including studies with different reference Member States.

Support from protocol design to study report – including post-study support and analysis of root causes and strategies for mitigation when study objectives are not met.

Efficient recruitment – the only Phase I CRO in Portugal, accessing a database of more than 14.500 healthy volunteers.

Agile – strong ability and successful track record of adjusting operations to accommodate short-notice changes, delays, adjustments.

Competitive per subject costs – located in Portugal, allows a great value for money offering.

Our Clinical Pharmacology Unit – Hospital-based and 'Inspection clean'

About BlueClinical – An Astrum Company

BlueClinical is a European CRO which has been successfully inspected by EMA authorities and US FDA. It has its own hospital-based 76-bed clinical pharmacology unit that is dedicated to the conduct of Phase I and proof-of-concept (Phase IIa) clinical studies in healthy volunteers and selected patient populations.

In late 2023, BlueClinical joined forces with three other established and respected European CROs, BioClever, Pharmalog and Popsicube, to form a new pan-European CRO: Astrum.

Astrum provides end-to-end clinical development services covering many therapeutic indications and all clinical phases.

Would you like to know more?

Contact us today and discover how we can support and streamline your process

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