



Clinical Sciences

Clinical Sciences includes activities such as discovery medicine, clinical trial management, data management, pharmacokinetics and statistical services, which span from the design and implementation of multi-faceted projects up to proof of concept, through the design and implementation of single areas within the client's clinical development plan.

Challenge

The pharmaceutical industry is undergoing major structural changes, and these changes will completely transform the industry's fundamental business models, core processes, and socio-techno-logistical infrastructures. One dimension of these changes is the increasing rate at which complex activities, including clinical development, are externalized. Nevertheless the design and implementation of complex clinical plans for new chemical entities requires integration of different disciplines, working knowledge of innovative experimental medicine as well as sound expertise in medical governance and regulatory requirements, timelines, quality and science. These remain among principal interests of both small biotech companies and large pharmaceutical organizations seeking to partner with contract organizations.

Aptuit Clinical Sciences Solution

Aptuit Clinical Sciences is engaged early in a clinical plan or study and offers industry-seasoned physicians, statisticians, pharmacokineticists, data managers, programmers, and trial managers with experience in multiple therapeutic areas across phase I-IV trials.

Aptuit's Clinical Science Group can provide support as early as during the conception of clinical plans (i.e. analysis of ICH, FDA, EMEA environment; analysis of differentiation factors and unmet needs; integrated analysis of preclinical & clinical data; established network of phase units / academic / clinical centers and KoL; due-diligence & In-licensing support). The Aptuit Clinical Science group has a well established expertise in translational and experimental medicine studies, including:

- Imaging studies
- Human laboratory models
- Challenge tests

Moreover, Aptuit's Clinical Science group has a proven track record in the design, conduct, analysis & interpretation of healthy volunteers & patient studies.

FIM studies

- Single-dose studies & repeated-dose studies
- Innovative design studies (FIM with enriched endpoints)
- Single and Fusion protocols

Safety Studies

- Sedation scales in FIM
- Multiple sleep latency test
- Cognitive tests, driving test
- Abuse liability (Specific tests in FTIH studies and Abuse liability studies)
- Vital signs standard in FIM
- Ambulatory blood pressure study, 24 hours Holter study
- PK/QT study, thorough QT study
- Drug-drug interactions
- Liver & renal impairment
- Special population (elderly, pediatrics, gender & ethnics)

Pharmacokinetics studies

- Simple and complex PK and distribution studies
- Bioavailability, food, and ADME studies

Efficacy & pharmacodynamic studies

- Proof of mechanism, proof of concept, and provision of evidence studies

Clinical science physicians provide medical input into efficacy and safety aspects of development plans / clinical studies:

Medical Monitoring

- Support global product development strategies
- Sponsor representation with regulatory agencies
- Contribution to study design, protocol, informed consent, investigator's brochure and other study-related documents
- Support to site personnel 24/7 on medical matters
- Medical review of statistical analysis plans and clinical trial reports
- Literature evaluation (disease background, competitor analysis)
- Clinical safety assessment of due diligence packages



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Pharmacovigilance

- Safety management planning
- Intake, processing, medical review of serious adverse events
- Global regulatory and investigators / IRBs reporting
- Preparation of PSURs, annual reports or end of study report
- Coding review

Integrated Preclinical and Clinical Safety assessment

- Review of preclinical safety packages
- Interpretation of preclinical findings and its relevance to man
- Definition of safety margins and safety risk assessment plan
- Selection of safe starting dose for FIM study
- Definition of safety monitoring plan and stopping criteria for FIM studies

IDMC Services

- Identification / recruitment of members
- Charter development
- Data analysis and preparation of IDMC Reports
- Meeting coordination / facilitation / minutes
- Provide IDMC recommendations to sponsors

Pharmacokineticists and statisticians both provide input on the selection of optimal study designs and appropriate level of blinding:

From Candidate selection to FIM

- Prediction of human pharmacokinetics (ie. CL, V, T 1/2) from preclinical species
- Estimation of dose(s) required to achieve team agreed therapeutic target
- Estimation of MABEL and toxicological coverage (input of predicted therapeutic index)

From FIM to PoC

- Data management support for clinical trials
- Sample size calculations for clinical trials
- Statistical and pharmacokinetic planning and analyses of standard and innovative clinical trials (including adaptive designs, fusion protocols and Bayesian approaches)
- Statistical and pharmacokinetic support for translational medicine studies
- Preparation of statistical analysis plan
- Data aggregation

- Non Compartmental PK analysis
- Modeling and simulation for dose escalation
- Population models (PK and PK/PD)
- Model-based approaches for dose selection
- Communication and interpretation of results

Other

- Due diligence and in-licensing support
- Statistical and pharmacokinetic consultation
- Development of predictive models

Clinical Trial Managers provide support with feasibility, set up, clinical conduct and result delivery:

Feasibility process

- Country / center / investigators evaluation and selection based on cost effectiveness, quality and timelines

Site management

- Site validation, initiation
- Investigator meeting
- Staff training
- Study file maintenance
- Monitoring and supervision of field monitors (CRAs)
- Recruitment strategy and risk management plans

Vendors and third parties selection and management

- Benchmarking and competitive bidding
- Contract development and performance metrics

Financial awareness

- Study budget set-up and maintenance
- Milestone and invoice tracking to ensure financial accuracy

Regulatory Knowledge

- Broaden knowledge of ethics and regulatory requirements and ICH Good Clinical Practices



Aptuit Verona

FACTSHEET



Clinical Sciences

Scientific Writing

- Scientific writing expertise to assist in the development of clinical study protocols, IB and associated study documents

Clinical Study Management

- Expertise in coordinating the activities and deliverables of internal and external partners by proactively identifying and resolving issues to achieve the successful completion of specific project goals in accordance with defined quality and time based metrics

All of these disciplines routinely share actions and activities together with the assigned project manager, which contributes in delivering the high quality services agreed with clients, timely and in full, with a high scientific level. The multi-disciplinary approach factors in clinical plans that are not the only factor of Aptuit Clinical Sciences: single activities provided as stand-alone services span from, i.e., PK and/or modeling and simulation activities, to medical writing, to third parts / vendors management.

Conclusion

The nature of the pharmaceutical industry now involves major structural changes and the management of clinical development risk. Aptuit Clinical Sciences not only offers a consulting service, yet a multidisciplinary approach, in an integrated environment, supplied with top level scientific knowledge, innovation, a sense of urgency and focused attention to timelines and client needs.

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from drug discovery through to market, including consultancy services, API development and manufacture, preclinical technologies, clinical sciences, pharmaceutical development services, large and small scale manufacturing, IVRS and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

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Engineering a better drug development process through scientific excellence.