ALTASCIENCES

CASE STUDY

STREAMLINING CROSS-SERVICE LINE OFFERINGS FOR ACCELERATED DRUG DEVELOPMENT

OVERVIEW

A sponsor approached Altasciences to design and conduct a bespoke preclinical PK/TK study in rats to obtain the required data to dose their Phase I first-in-human (FIH) clinical trial by the end of the same year, an extremely ambitious target. This case study examines how Altasciences' comprehensive service offering, expertise, cross-service collaboration efforts, and solid communication strategies resulted in a positive outcome.

BACKGROUND

The sponsor was developing an extended-release formulation for a compound that had already received market approval. They planned to proceed directly to an Investigational New Drug (IND) submission using data from the original formulation, obtain authorization to proceed, and then begin dosing the first clinical subjects by year end. However, during a pre-IND meeting early in the year, the Food and Drug Administration (FDA) indicated that additional preclinical toxicology and PK/TK data were required.

ESTABLISHING CLEAR EXPECTATIONS

Internal Team Alignment

The study was overseen by an Altasciences' study director and the global advisory team. A dedicated program manager (PgM) was also assigned to ensure a smooth and coordinated approach. The PgM hosted a comprehensive kick-off meeting that brought together all of Altasciences' internal operational teams, including preclinical study direction, medical writing, regulatory, clinical project management, program management, and business development. This meeting was instrumental in aligning objectives, establishing clear communication protocols, setting expectations for communication, and developing detailed, actionable timelines.

Sponsor Alignment

In a subsequent kick-off meeting, the sponsor and Altasciences' PgM established a shared commitment to ensuring efficiency and clear communication throughout the project. Both parties agreed to implement expedited writing and review cycles, ensuring rapid turnaround times for documents and feedback. They also prioritized prompt responses to email communications and active participation in all meetings. This collaborative approach fostered a dynamic and agile working relationship, enabling both teams to quickly adapt to challenges and maintain timelines throughout the study.

INTEGRATED PROGRAM EXECUTION: ALIGNING EXPERTISE, COMMUNICATION, AND PROCESSES TO MEET ACCELERATED CLINICAL TIMELINES

Optimizing Preclinical Insights for Accelerated Clinical Trial Initiation

The program benefited from the involvement of an Altasciences subject matter expert with extensive experience in designing translational safety studies to meet the sponsor's specific goals and facilitate faster start-up times for clinical trials. Additionally, Altasciences' PgM with expertise in conducting preclinical studies and initiating clinical studies played a key role in the program. This collaborative approach enabled continuous and timely guidance to the sponsor regarding emerging preclinical data and efficient knowledge transfer across Altasciences' medical writing (MW), scientific and regulatory affairs (S&RA), and regulatory teams. This collaborative approach allowed for seamless information integration into the documents required for the first-in-human clinical trial.

Focused Collaboration for Seamless Preclinical-to-Clinical Transition

Altasciences' PgM guided the team by breaking down the preclinical timelines into very detailed steps, showing exactly when quality-controlled draft data would be available, when unaudited draft reports would be available, and when audited reports would be issued. This sharp focus on the preclinical phase of the program allowed the team to meticulously review their tasks, identify the earliest they could start their work, and determine where they could save time. Collaboration among the cross-functional teams allowed regulatory document preparation and clinical start-up tasks to be completed in parallel with preclinical report writing. This included our PgM and clinical project manager working together to ensure collaboration amongst our entire team, resulting in a smooth transition from the preclinical study into the clinic.

Investigator's Brochure and Protocol Development: A Case of Parallel Processing and Adaptive Planning

- **Overcoming the Challenges**
  - Timelines for the Investigator's Brochure and clinical protocol development were drafted with built-in flexibility, and our team was made aware that dates were tentative and dependent on data availability. To minimize the risk of missed milestones, a contingency plan was created to mitigate the impact of delays in providing preclinical data. This included close communication between Altasciences' PgM, preclinical team, and writers preparing the clinical documentation, so updates and foreseeable risks would immediately be communicated, allowing for workloads and timelines to be adapted accordingly.
  - The dynamic flow of information from many internal and external sources had to be collected and incorporated into the final deliverables. Our team demonstrated exceptional adaptability, document management, and communication skills while collecting, interpreting, and incorporating all information sources into their documents.

- **Driven by Process Excellence**
  - The successful delivery of required documentation was driven by our team's collective focus and dedication, enabling the timely completion of both the IB and the clinical protocol. The program's overall success relied on aligning our internal objectives with the sponsor's—an approach that ensured high-quality deliverables and a high level of sponsor satisfaction. Our team maintained an efficient flow of information between departments and sponsor throughout the drafting process.
  - The superior quality of the end products was achieved because of diligent review cycles and open dialogue with subject matter experts throughout the drafting process.

Effective Meetings Strategy

A well-structured meeting strategy was set up with the internal team and the sponsor.

Internal Meeting: Intended for discussions across the entirety of the Altasciences project team(s)—i.e., preclinical tox site(s), pharmacology/PK analysis, medical writing, S&RA, regulatory/IRB submissions, global advisor(s), and program/project management. This allowed team members to address issues and challenges collaboratively across multiple services, reducing the need for lengthy email exchanges or numerous phone calls.

Sponsor Team Meeting: To adapt to the sponsor's communication preferences, our team tailored a communication plan for the project that aligned with the sponsor's expectations. At the sponsor's preference, routine weekly updates and timelines were provided by the PgM, and meetings were held ad hoc. Additionally, the tox, MW, S&RA, and regulatory teams continually communicated with the sponsor about their responsibilities and deliverables, keeping our team in copy. It was also understood that if an urgent issue arose, it would be prioritized and we would ensure to meet within 48 hours (in most cases, meetings occurred within 24 hours). All meetings were specific and focused on specialized points for the functional group to address. This approach encouraged active participation and eliminated vague discussions.

CONCLUSION

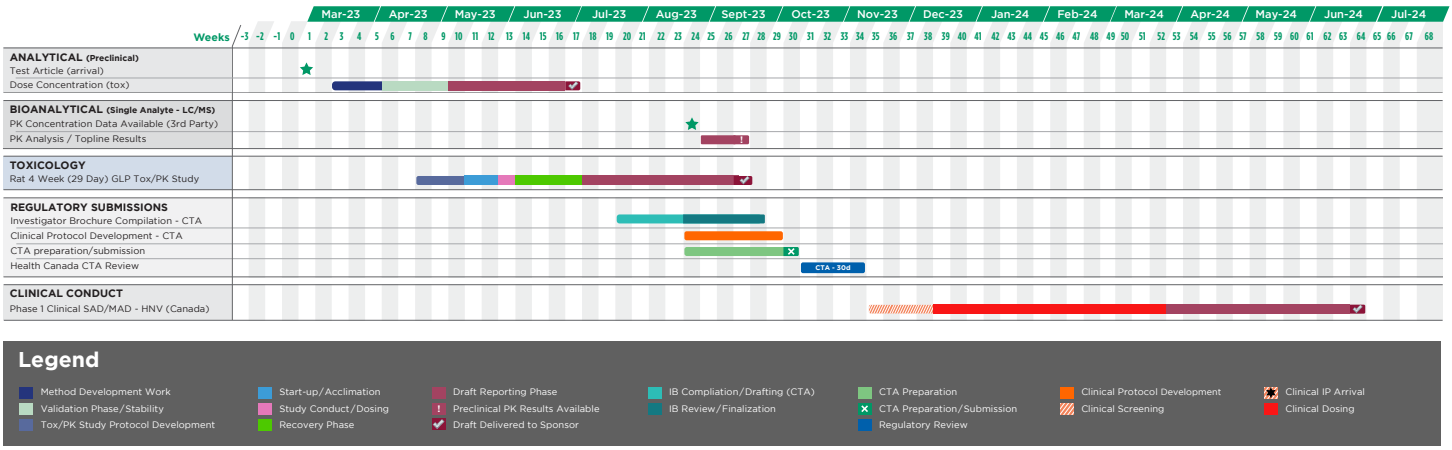
Altasciences achieved the sponsor's key performance indicator (KPI) of dosing the first clinical subjects with their novel compound by the end of the year. After attaining the KPI, our team's attention shifted to the remainder of their respective timelines, ensuring continued communication and efficiency throughout the program's duration.

The strategies outlined above resulted in a timeframe of approximately seven months from dosing the preclinical PK study to dosing the first subjects in the clinical study (see Appendix 1 for a Gantt chart outlining the timeline of events). This included but was not limited to completing the in-life and post-life activities of the preclinical study, drafting the PK and toxicology reports, analyzing the data, drafting the IB, writing and finalizing the clinical protocol and Informed Consent Forms, collating and submitting the regulatory package, waiting for the regulatory review/approval, and screening and dosing subjects.

Contact us **today to get your program started.**

Appendix 1: Preclinical to Clinical Gantt/Timeline of Events

Preclinical to Clinical Dosing Gantt



ABOUT ALTASCIENCES

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 30 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.