celerion
Translating Science to Medicine

CASE STUDY | DRUG-DRUG INTERACTION STUDY

RUSH-ORDER DDI STUDY? CELERION CAN DELIVER!

NEED

- A biotech company needed to complete a drug-drug interaction (DDI) study to support their market application.
- The client was seeking a full-service CRO to expedite a DDI study with a strong and moderate CYP inhibitor.
- They required quick study-start up and reporting to meet their submission timelines, therefore the compressed timeline made this a true "rush-order" study.

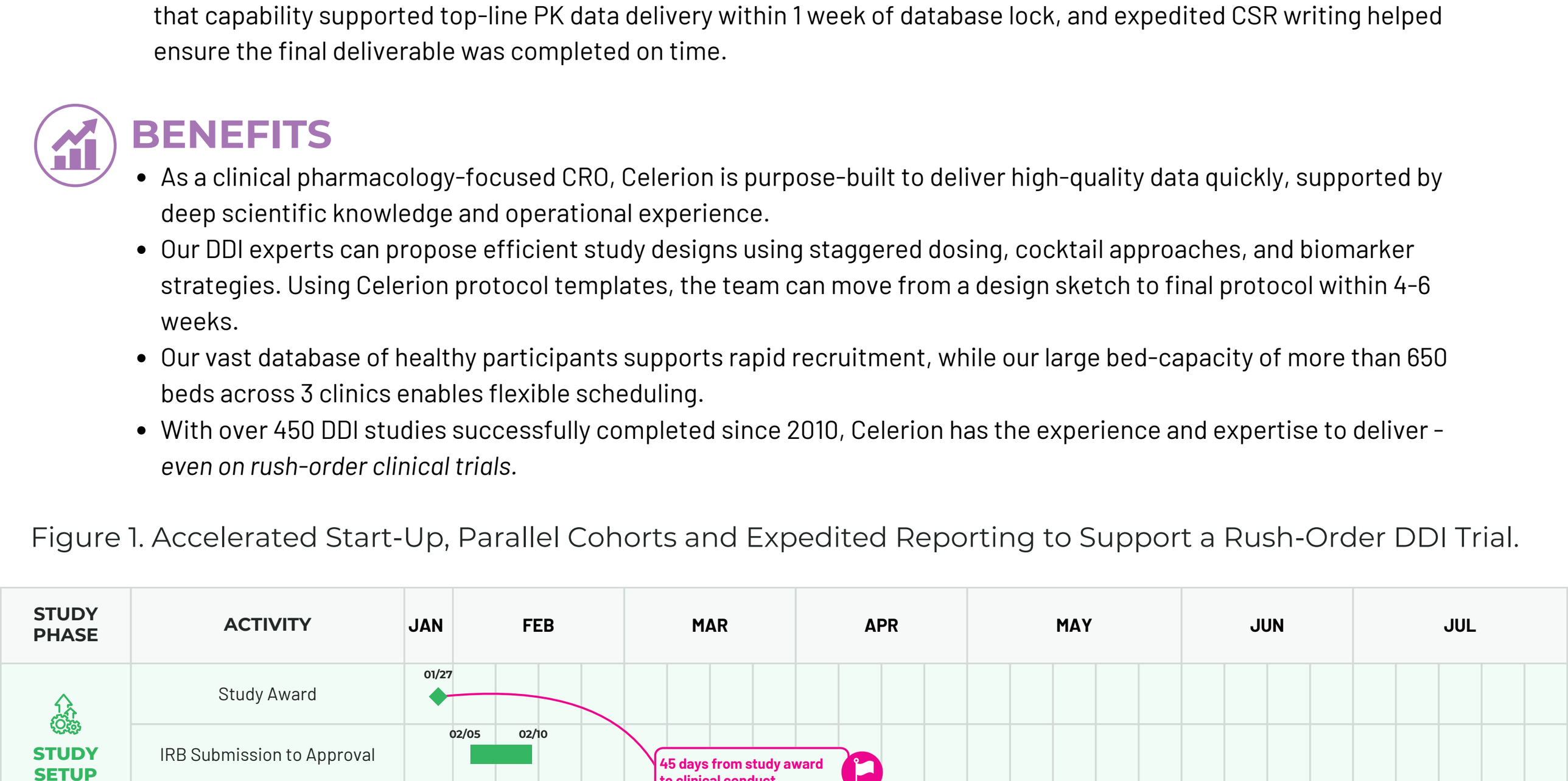
APPROACH

- Celerion operational specialists and the Principal Investigator closely collaborated with the client to **optimize the study design** and accelerate start-up timelines. As such, clinical conduct began within 45 days of study award.
- Backed by a **strong track record of on-time enrollment**, recruitment and screening was completed for each cohort within a couple of days.
- Running the strong and moderate inhibitor **cohorts in parallel** (Cohort 1 and 2, respectively) expedited the clinical conduct portion of the study.
- Our standard process is to offer **ultra-rapid database lock within 5 days** of the last participant visit. For this study, that capability supported top-line PK data delivery within 1 week of database lock, and expedited CSR writing helped ensure the final deliverable was completed on time.

BENEFITS

- As a clinical pharmacology-focused CRO, Celerion is purpose-built to deliver high-quality data quickly, supported by deep scientific knowledge and operational experience.
- Our DDI experts can propose efficient study designs using staggered dosing, cocktail approaches, and biomarker strategies. Using Celerion protocol templates, the team can move from a design sketch to final protocol within 4-6 weeks.
- Our vast database of healthy participants supports rapid recruitment, while our large bed-capacity of more than 650 beds across 3 clinics enables flexible scheduling.
- With over 450 DDI studies successfully completed since 2010, Celerion has the experience and expertise to deliver - *even on rush-order clinical trials.*

Figure 1. Accelerated Start-Up, Parallel Cohorts and Expedited Reporting to Support a Rush-Order DDI Trial.



◆ Diamonds represent key milestones. ▬ Bars represent start/stop dates.

CSR, clinical study report; IRB, institutional review board; PK, pharmacokinetics; SIV, study initiation visit. * including Sponsor review time

RESOURCES:

- Expert Drug-Drug Interaction Study Design and Conduct
- Cocktail DDI Fact Sheet