CROSS ALLIANCE®
Contract Research Organisation for Scientific Services

ACCELERA
PART OF NMS GROUP

PRE-CLINICAL TO CLINICAL
A SEAMLESS & INTEGRATED SOLUTION

Moving from pre-clinical to early clinical phase is always a critical and challenging step in drug development.

ACCELERA and CROSS are suggesting a solution to this, with the aim to offer an efficient time & cost saving solution, if possible, with improved outcome.

After the completion of the pre-clinical phase, the obtained data need to be reviewed and the relevant safety and PK information translated into the design of the First in Human (FIH) study protocol. This crucial step usually requires considerable time and the involvement of different experts, often adding external consultancy costs.

Collaborating together, ACCELERA and CROSS offer to bridge this gap, speeding up and economizing the process.

In addition, and with an often underestimated impact, the analytical methods developed for pre-clinical safety studies have to be re-developed for the human matrix (plasma or serum & urine). Typically, this has to be done in a different facility that would need to start from the scratch with method set up and validation. Again, extra time has to be accounted and additional money invested.

Of course, if you are engaged with large-sized fully integrated preclinical and clinical Contract Research Organizations (CROs), probably an internal translational team is available to satisfy this need and streamline the process from pre-clinical stage to FIH.

For several reasons, not all projects from small to mid-sized BioTech and pharma companies are handled by multinational CROs active from pre-clinical to clinical. Sometimes the tailored and customized work provided by smaller CROs, both in the pre-clinical and in the clinical field, could better fit with your company soul or your investments allowances.

The synergy between ACCELERA and CROSS can provide a focused, custom tailored, integrated translational process for you.

A new opportunity on the market

ACCELERA and CROss Alliance® are two small-medium sized international CROs, specialised in pre-clinical and early phase clinical development, respectively. Both companies have been on the market for decades. Despite being located in different countries, Italy and Switzerland, due to the close distance (about 1 hour by car), they know each other very well and have collaborated on different projects in the past.

Today the management of the two companies decide to move a step forward and integrate their offer into a **FIM translational package,** on selected projects.

The aim is to work in parallel and bring the respective expertise into a joint team, in order to achieve:

- ✓ Time saving by
  - bridging the gap between pre-clinical and clinical phases. Depending on the type of request, at the end, as a Sponsor, you will obtain: the Investigator's Drug Brochure, the Clinical Synopsis and, if needed, a Clinical Site(s) Feasibility evaluation, ready at the time the pre-clinical IND enabling program is completed.

- ✓ Secure early integration of the pre-clinical information and knowledge into the Clinical Study Synopsis under drafting. This could allow:
  - early awareness of the pharmacology and toxicity mechanism of the test item;
  - integrated evaluation of formulation options to gain a clear view of the entire path through preclinical and clinical studies;
  - available predictable animal PK/PD models at ACCELERA, that will interactively support CROSS clinical PK experts in the determination of the optimal dosing regimen;
  - early consideration of biomarkers to guide patient selection, and to monitor efficacy and safety endpoints.

- ✓ Costs saving by
  - combining the bio-analytical method development & validation in both animal and human matrices;
  - free information transfer and scientific support between ACCELERA's Program Manager and CROSS' Medical Writers;
  - no overheads for this seamless service.

- ✓ Assure simplicity and transparency as the two parts, the pre-clinical development at ACCELERA and the clinical phase(s) at CROSS, will be offered, negotiated and contracted separately without any umbrella arrangement.

- ✓ Assure engagement, since before committing ourselves, both CROSS and ACCELERA will evaluate if the clinical indication targeted and the pre-clinical requirements of the project fall into the respective field of competence and experience.

To achieve all of this the two packages should be ideally discussed, negotiated and contracted in parallel to win the synergies from the very start.

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About ACCELERA

Accelera is a premium tier Contract Research Organization (CRO), developing and offering new technologies and integrated programs to pharmaceutical and biotechnology companies around the world to move forward their innovative drug candidates from early discovery to the clinic.

Built on decades as part of the international pharmaceutical industry, Accelera provides specific competence and tools to help Companies in predicting and managing potential pharmacokinetic, metabolic, and toxicity issues, adding real value to Company's R&D programme.

Major services available at Accelera include:

- ✓ High-throughput preclinical profiling and in silico ADMET prediction and modelling;
- ✓ IND/CTA enabling packages, including GLP general toxicology, safety pharmacology, genotoxicity, ADME and pharmacokinetics (PK);
- ✓ Toxicology and ADME/PK studies in rodent and non-rodent species, including Nonhuman Primates (NHP);
- ✓ Bioanalysis and pharmacokinetics for preclinical and clinical studies, including assay development and validation, PK/PD, and population PK data analysis;
- ✓ Drug disposition packages, including the synthesis of radio-labelled compound and QWBA;
- ✓ Preclinical development consultancy and preparation of regulatory documentation.

Accelera currently employs more than 50 scientists and about 55 technical staff skilled in multiple preclinical disciplines (drug safety, pharmacokinetics, bio-analysis, analytical biology, drug metabolism and distribution).

Accelera facilities are fully GLP and AAALAC accredited.

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About CROSS ALLIANCE

CROss Alliance® is the commercial brand name for CROSS Research SA: a private, Swiss, regional, Contract Research Organization (CRO), active in the field of early clinical drug development.

CROSS Research SA performs low risk phase I studies in its own facility located close to Lugano (CH) while coordinates and manages Phase I - III trials in European clinical sites with the requested competence for each project.

Since 1996 CROss Alliance® companies have performed approximately 500 clinical studies and delivered valuable data, often used for regulatory purposes all over the world, to more than 100 Sponsors.

Specific experience in PK, BA, and early phase studies

- ✓ Phase I safety and pharmacokinetics trial expertise in healthy volunteers with more than 380 studies performed, including first in man;
- ✓ Regulatory submission and trial management in different EU Countries is part of daily work due to the ownership of an internal phase I unit and continuous interactions with ECs and CAs;
- ✓ Availability in house of a clinical pharmacologist (Principal Investigator & Medical Director at CROSS Research phase I unit);
- ✓ CROSS Research Sr. Medical Writers belong to European Medical Writers Association and hold advanced certification;
- ✓ Internal pharmacokinetic expertise and internal pharmacokinetic data analysis;
- ✓ Internal biometry department which offers higher C-DISC and C-DASH standards, fully validated Oracle Clinical DB, different possibilities of EDC or paper CRF according to trial needs and support in case of Regulatory inquiries;
- ✓ Internal Quality Assurance Unit headed by certified BARQA Level II Auditor who acted also for many years as coordinator of the GCP working group at GIQAR (Italian Research Quality Assurance Society).