Clinical Development Aspects

The current regulatory guidances highlight the importance of pharmacokinetic assessments in patients with hepatic insufficiency in the drug development (FDA 2003, EMA 2004).

Early phase I/II hepatic PK investigations are essential for the conception of later stage trials and with regard to the marketing authorisation and label.

Special aspects of hepatic impairment trials need attention:

Vulnerable study population: Patients with hepatic impairment as well as elderly matched controls typically suffer from concomitant diseases and require intensified care.

Instability of the disease: Collaboration with hepatologists and well established medical records are of importance to identify the right study population.

Measurement of hepatic function: Infrastructure and experience in different hepatological diagnostic methods (e.g. Fibroscan, ultrasound, antipyrin clearance) are important to reliably assess liver function and clinical endpoints.

Hepatic Impairment Expertise At CRS

CRS is recognised by the authorities as one of the top CROs regarding clinical trials involving patients with hepatic insufficiency.

Since the early 90s, CRS has realised more than 100 trials in patients with hepatic impairment and is running currently approximately 5-8 hepatic impairment trials per year.

All trial concepts are being accomplished according to the relevant and effective FDA/EMA guidances and are conducted under highly standardised phase-I conditions - most of them monocentric in own CPUs, specialised in the recruitment and care of patients.

The successful conduct of the trials and the availability of suitable patients are based on 3 decades of experience of the CPUs lead by internist Dr. Atef Halabi, and on a reliable network with university clinics as well as external medical centers and specialists.

This setting and track record make CRS the preferred partner by both big pharma and small biotech companies when it comes to hepatic impairment trials.
Hepatic Impaired Patient Trials - A Success Story At CRS

Accelerate Your Development - Your Advantages At CRS

The long lasting and broad experience with hepatic impairment PK trials allows CRS to find individualised strategies and tailored design solutions for a fast and successful development of your product. Your advantages at CRS comprise:

- **Fast and reliable recruitment:** The close vicinity to the University Medical Centres in Kiel and Lübeck and an intensive cooperation with the treating physicians of the hepatology outpatient clinic (1000 patients per year) as well as with external specialists, allow CRS to provide high numbers of suitable patients with well established medical records.

- **Short approval timelines:** 30 days from submission to approval due to CRS’s monocentric approach and parallel submission to CA and EC/IRB.

- **Fast trial conduct:** Average duration 4-6 months (FSI-LSO).

- **Safety:** The infrastructure and expertise enable CRS to work according to the best ethical and medical practice with special regard to the vulnerable study population.

- **High standardisation:** Monocentric conduct of complex PK trials, avoiding inter-centre variability and guaranteeing highest quality according to phase-I standards.

Exemplary List Of Hepatic Impairment Studies Performed By CRS

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