Clinical Trials Support in EU

ASPHALION
Knowledge from experience

Over 20 years of experience assisting companies access clinical trials and during clinical trials development.

Strategy / SA with NCAs

- **Consultation with a Competent Authority** via **Scientific Advice** of the preclinical plan and the Clinical study design.
- **Non-Clinical/Clinical/ CMC Consultancy** to initiate and during the trial.

IMPD / IB Writing

- **Full Writing of IMPD sections** for all product types and Clinical phases:
  - DS, DP, and placebo sections.
  - Non Clinical.
  - Clinical and R&B.
- **IB Writing.**

CTA via CTIS and trial regulatory activities

- **CTIS Submission:** Parts I and II (for new trials and trasitions).
- Support until **validation and assesment of RFIs up to approval.**
- **Trial Life-Cycle Management** (ammendments, responses to RFIs, notifications).
- **Transparency** requirements.
- **Local expertise.**

Drug Safety management

- **Safety Management Plans.**
- **Database** maintenance.
- **SAEs and SUSARs** management.
- SUSARs **notifications**.
- **DSURs/ASRs** elaboration and submission.
- **Line listings and Case reconciliations.**

+ Necessary registrations for interactions and for CT:

- **SPOR (OMS/SMS)**
- **xEVMPD**
- **IRIS**
- **RPI number**

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