

EU RA consultancy during Research and Development

A key milestone of any early development of a candidate medicinal product is the preparation for a Clinical Trial Application for the First in Human (FIH) clinical trial and subsequent Phase-1, Phase-2 and Phase-3 clinical trials. PhaRA's experts will assist you and will also help assuring that the EU Pediatric Regulation Requirements are met timely, that options of Orphan Drug Status are capitalized on, and that during the whole development, maximal opportunities are taken to ensure regulatory authority input is sought through Scientific Advice procedures.

For more information see:

Early-phase development

Clinical Trial Applications (CTA)

Scientific Advice (SA)

Pediatric Investigation Plan (PIP)

Orphan Drug Designations (ODD)

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