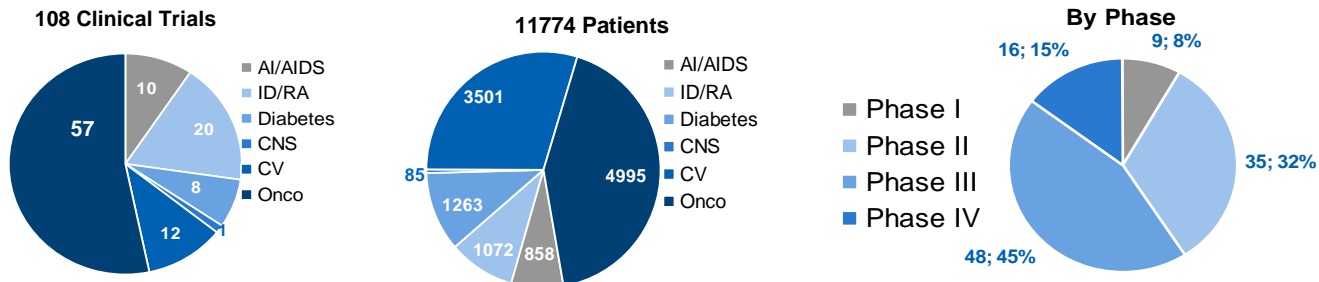


PIVOTAL : CLINICAL OPERATIONS DIVISION

■ *The Team*

- Life Sciences Graduates, mainly MPharm.
- Organization by Therapeutic Areas.
- Average Experience: 5 years (range: 0,6 – 15 years).
- SCRM's (Senior Clinical Research Managers) / LCRAs (Lead Clinical Research Associates) / SCRAs (Senior Clinical Research Associates) / CRAs (Clinical Research Associates) / CTAs (Clinical Trial Assistants).

■ *Experience*



■ *Services offered*

TACTICAL IMPLEMENTATION CLINICAL STUDIES

- Specialisation in therapeutic areas: Oncology, CV, Endocrinology, CNS, Immunology, Infectious Diseases
- Monitoring International and Local Clinical Trials from Phase I to Phase IV, including FIH trials
- Monitoring EPIs / PMS studies
- Feasibility / Selection of Sites / Investigators
- Investigators Meetings Management
- Studies performed according to ICH-GCP and Pivotal / Sponsor SOP's

CLINICAL START-UP UNIT

- Preparation / Submission of Clinical Trials and PMS to Ethics Committees and Health Authorities
- Contract negotiations and Sign off
- Broad experience in Clinical Trials approved under the EU Directive

INSOURCING

CRAs / SCRAs / CTAs based in Pivotal's Office, Sponsor's Offices or Regional Home-Based

