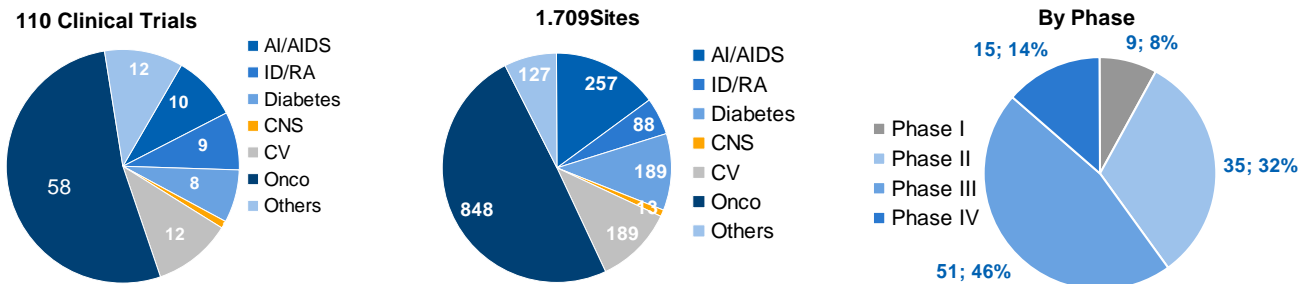


# PIVOTAL : CLINICAL OPERATIONS DIVISION

## ■ *The Team*

- Life Sciences Graduates, mainly MPharm
- Organization by Therapeutic Areas
- Average Experience: 4 years (range: 0,6 – 16 years)
- SCRM (Senior Clinical Research Managers) / LCRA (Lead Clinical Research Associates) / SCRA (Senior Clinical Research Associates) / CRA (Clinical Research Associates) / CTA (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

CRA / SCRA / CTA based in Pivotal's Office, Sponsor's Offices or Regional Home-Based

