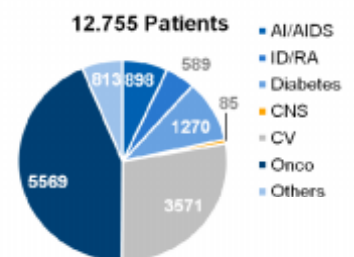
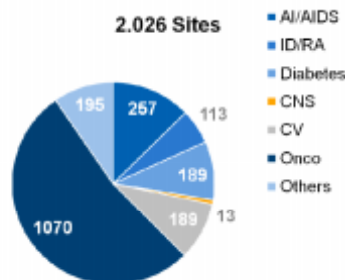
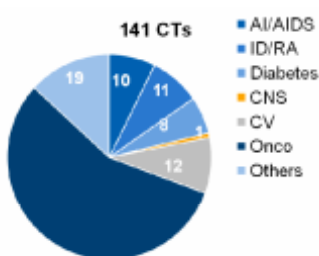


# PIVOTAL CLINICAL OPERATIONS DIVISION

## ■ The Team

- Life Sciences Graduates, mainly MPharm
- Organization by Therapeutic Areas
- Average Experience in Clinical Research: 5 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

### 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

### 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 SOPs

### INSOURCING

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

