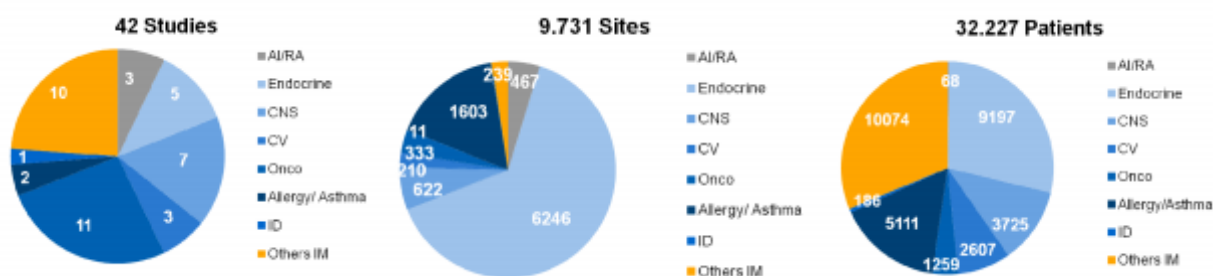


# PIVOTAL OBSERVATIONAL STUDIES UNIT

## ■ *The Team*

- Life Sciences Graduates, mainly MPharm
- Dedicated LCRAs (Lead Clinical Research Associates) / SCRAs (Senior Clinical Research Associates) / CRAs (Clinical Research Associates) / CTAs (Clinical Trial Assistants) / DECs (Data Entry Clerks) / DMs (Data Managers) / BS (Biostatisticians)

## ■ *Experience*



## ■ *Services offered*

### STRATEGIC & TACTICAL SERVICES

#### 1. Strategic advice on studies: methodology and design

- Medical and Biostatistical

#### 2. Management of Clinical Operational Aspects

- Preparation / Submission to Ethics Committees and Health Authorities under new Directive
- Contracts negotiation
- Investigators Payment Management

#### 3. Source Data Monitoring: as needed

#### 4. Data Management

- Oracle Clinical Version 4.5.3
- eCRF: design
- CRF reception
- Data Bases: design / development / validation / maintenance
- DCFs (Data Clarifications Forms) Generation

#### 5. Biostatistics

- SAS Version 9.2
- Statistical Analysis Plan and Final Statistical Report