ClinSearch
Strategic consultancy
Clinical evaluations
Full-service CRO
Early access programs
Reimbursement
Since 1999

ClinSearch

22 Nationalities

70 staff members (MS, PhD, MD, PharmD) speaking 13 languages

26 years experience

830+ projects

- Pharmaceutical
- Medical devices
- Public Health
- Diagnostics

All major therapeutic areas

Europe, Middle East, USA
Covering 30+ countries
From Proof of Concept to Early Access & Post Market surveys

- 70 projects per year
- 70% split activity private/public
- 37+ market access projects since 2016

ISO 9001, ISO 27001, ISO 27701 & HDS certified

NUMÉRIQUE LNE CERTIFICATION 27001
NUMÉRIQUE LNE CERTIFICATION HDS
NUMÉRIQUE LNE CERTIFICATION 27701

TÜVRheinland CERTIFIÉ
Système de management ISO 9001:2015
www.tuv.com ID 9105068017

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ClinSearch
Supporting your innovation

Full-Service CRO

Full service and *à la carte* solutions

Data Collection

SNDS Pairing

Medicine Acceptability

Statistics & Medical Writing

Regulatory affairs, Market Access & HEOR

Clinical Operations

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Conceiving and implementing the best strategy for *your* clinical evaluation

Tailored Solutions
To your needs, at your stage

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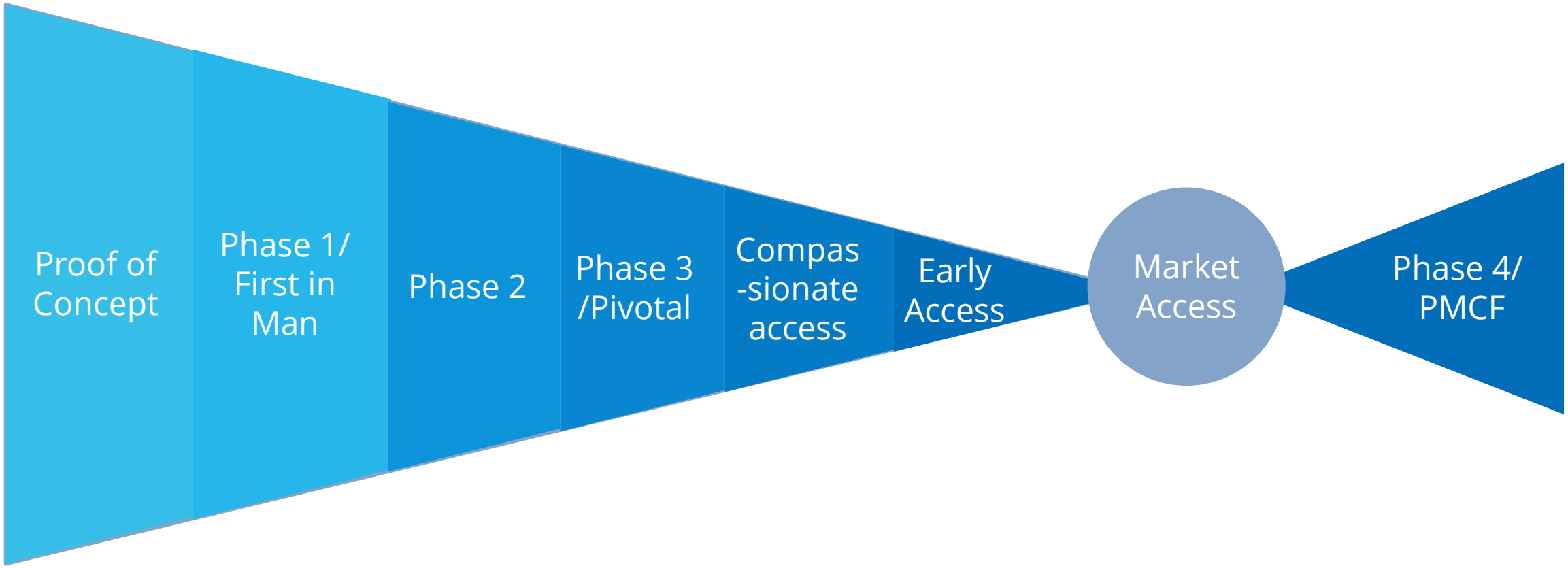
From 1 patient to 220,000 subjects enrolled



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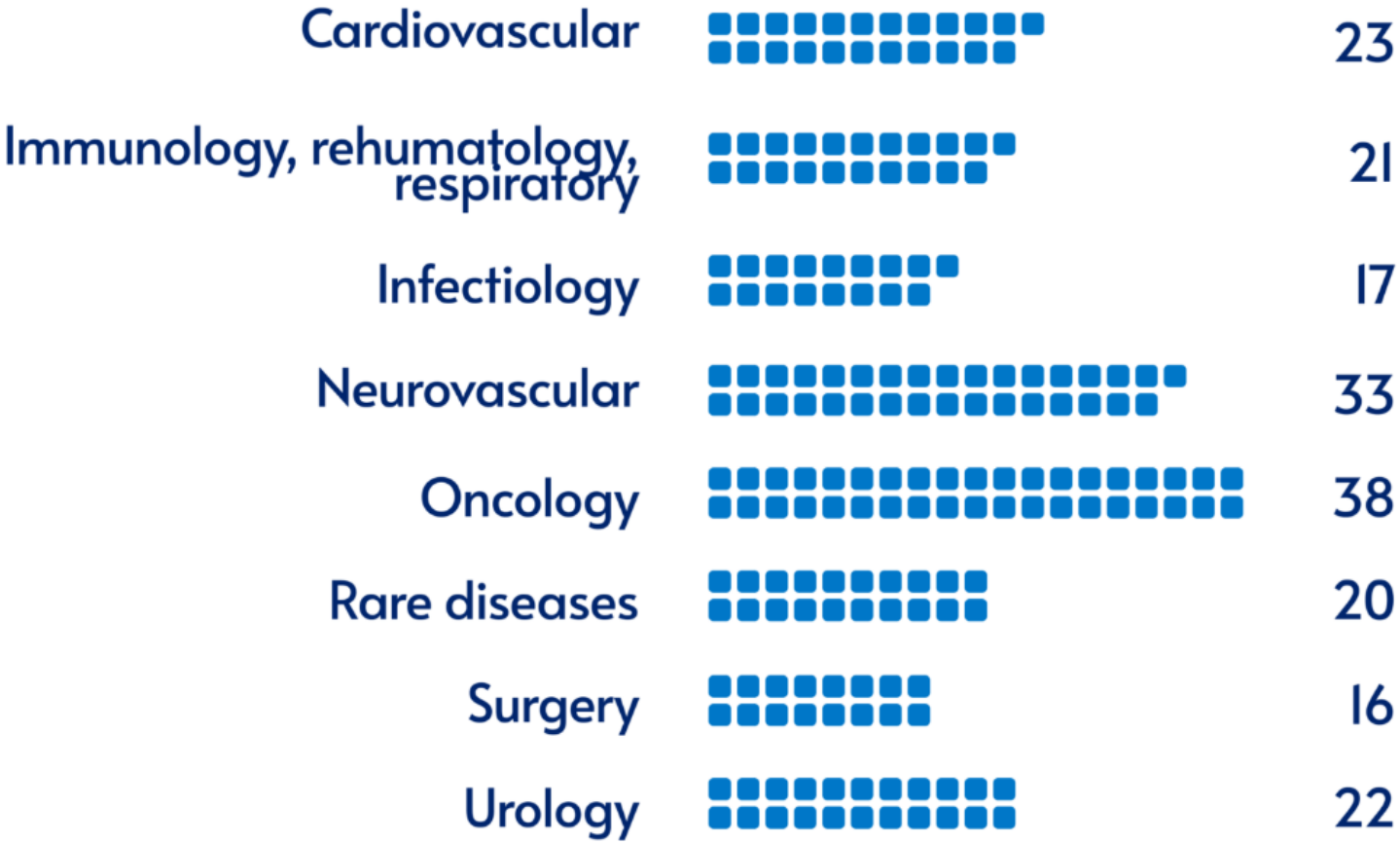
Relevant experience



Top 10 therapeutic areas of expertise (by # projects since 2016)

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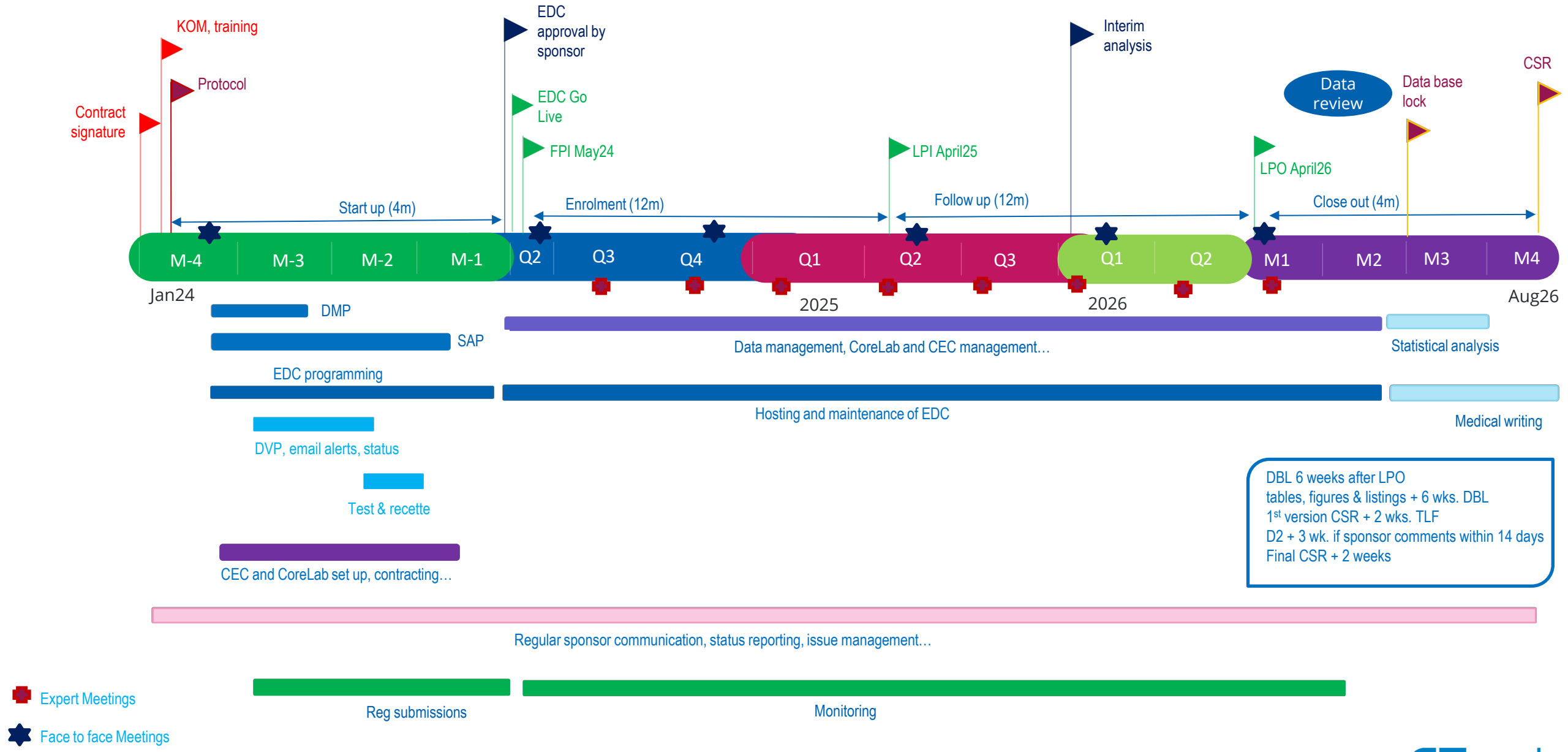
Example study timelines



The team

CLIN OPS

20 + team members including Senior Director MD & Drug Development, Deputy Director, 5 Project Leaders, 4 Deputy Project Leaders, 12 CRAs/Country Specialists (8+ languages), 2 CSO

REG AFFAIRS

Global Regulatory Affairs Director, DPO

SCIENTIFIC ADVISORY & STATS

10+ team members including Scientific and Medical Advisors, Research Scientists, Medical Writers, Biostatisticians, Epidemiologists, Health Economist and SAS Programmers

IT / DM

10+ team members including Senior Director IT/IS, Master Data Managers, JAVA Developers, IT Administrators, SAS Programmers, IT Engineers and Software Quality Engineer

NEUROPSY

13 neuropsychologists part of team on national registry study

SUPPORT

Quality Affairs Manager, Financial Manager, Business Development, Admin

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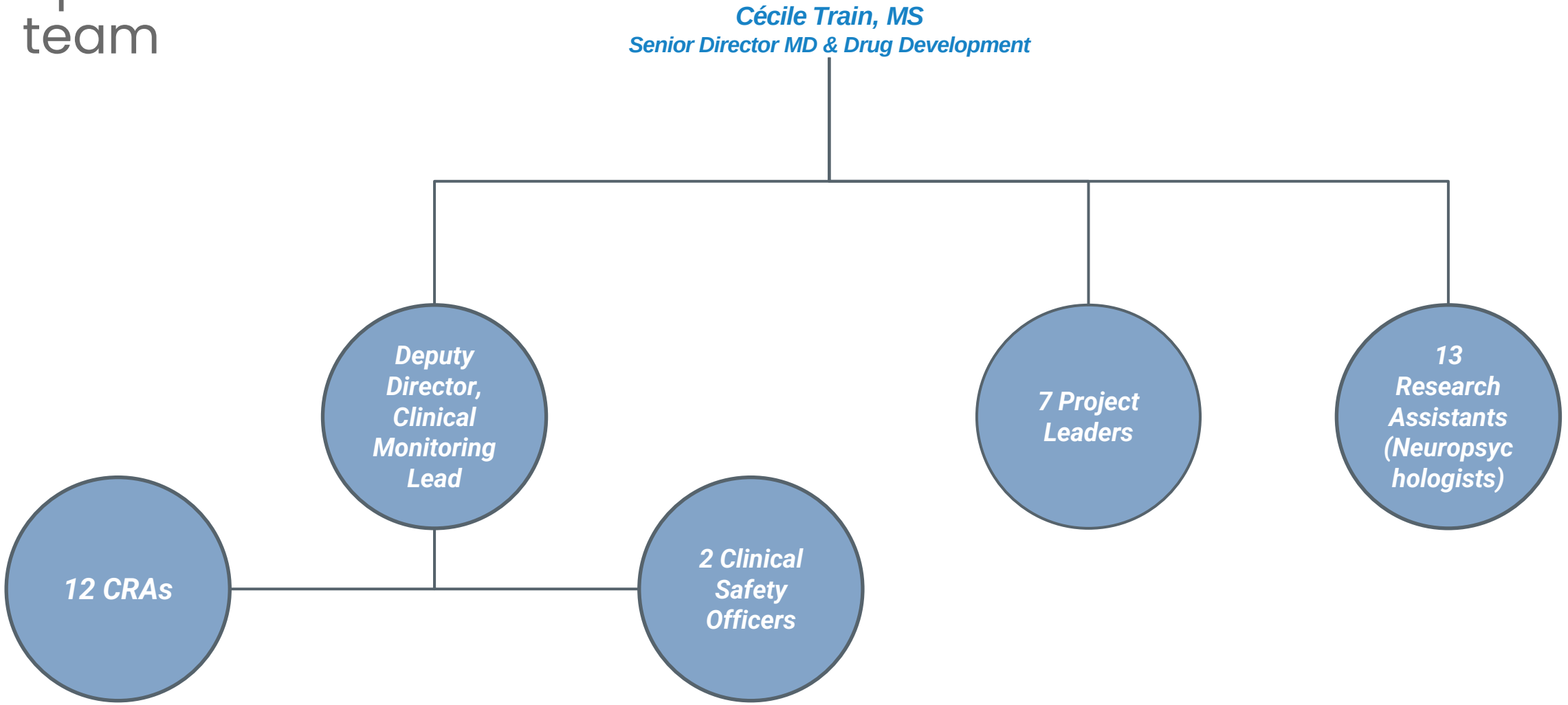
Clinical operations team



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Regulatory Affairs

Team: Global Regulatory Affairs Director, DPO

DPO & Data protection activities

European focus:

- 50+ submissions per year
- 98% success rate

Regulatory vigilance process

Key Solutions:

1. Country/Site mapping with MD & Drug Development department; study feasibility analysis in EMEA.
2. Study document regulatory adaptation.
3. Submissions to ECs and CAs in EMEA.
4. PIA and Data Protection Agency Submissions (France).
5. Submissions of protocol amendments, renewals, safety reports, close-out notifications.

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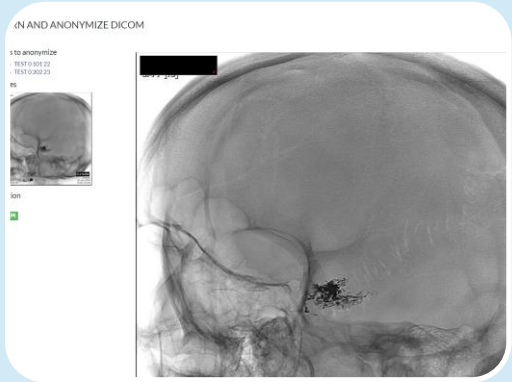
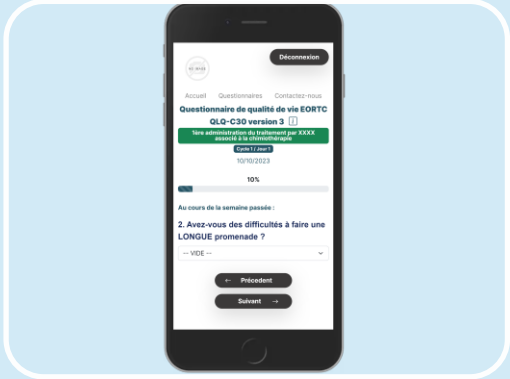
Reimbursement & HEOR services

- **Core reimbursement and pricing dossier**
- **Comprehensive reviews of evidence**
- **Modelling of healthcare interventions and outcomes**
- **Micro-costing analyses**
- **Analytic modelling for decision-making processes**
- **Systematic reviews and meta-analyses**

Data Management: EDC, ePRO, customized tools





EDClin™:
Web application (responsive design) based on Oracle & Jakarta EE.

Developed following GAMP 5, Good Data Management Practices, GDPR and FDA 21 CFR - Part 11 standards

DMS functions

(DICOM, images, photos, video, PDF…)

PROMs/PREMs

Electronic or paper support (PWA, app stores…)

EDClin
Easy Data Capture

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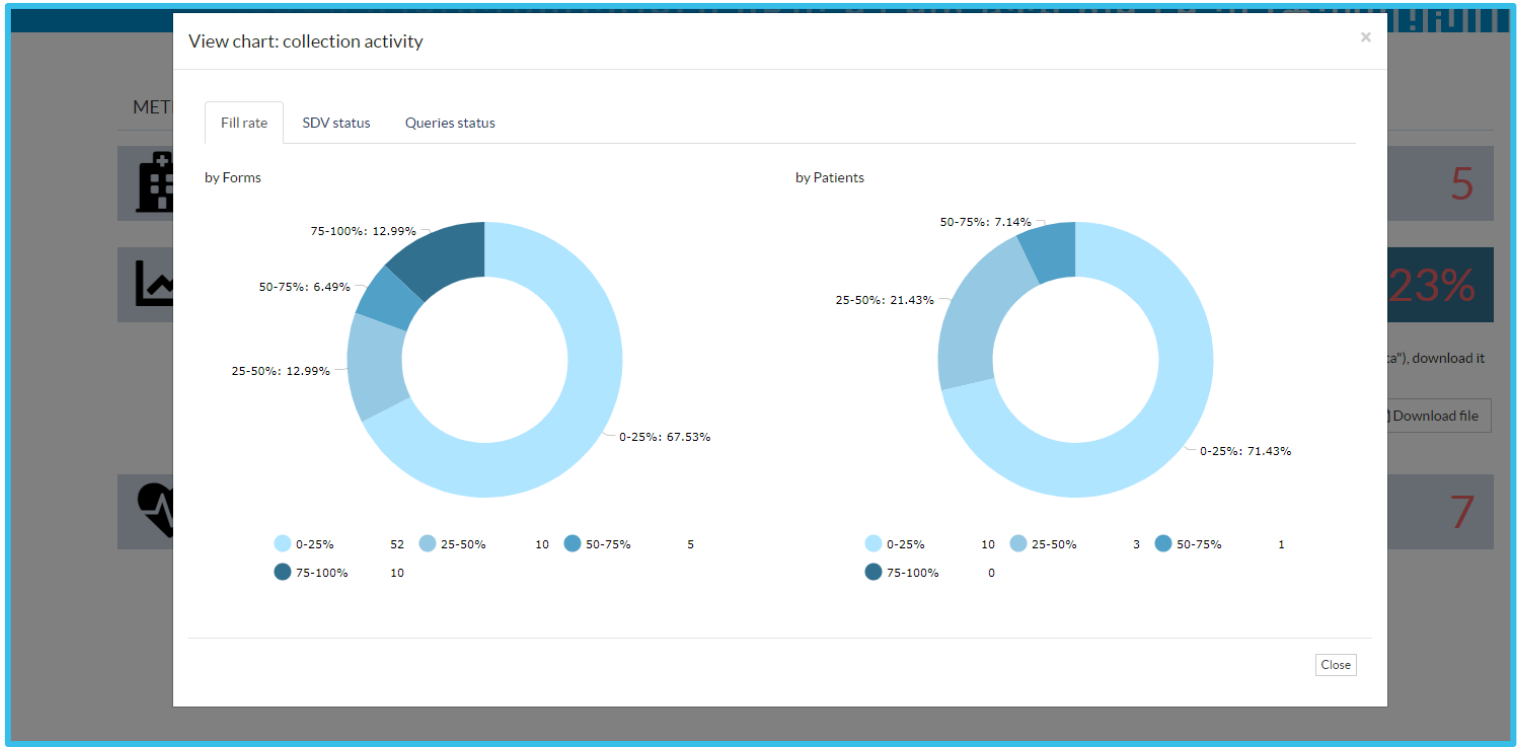
ClinSearch
Supporting your innovation

EDClin™

Sponsor's view



- Core Lab & CEC data in one place
- Global status
- Notifications by e-mail (PV, inclusions…)
- Detailed metrics (Excel, online graphics)
- Data extraction (SAS®, Excel)
- eCRF Read view

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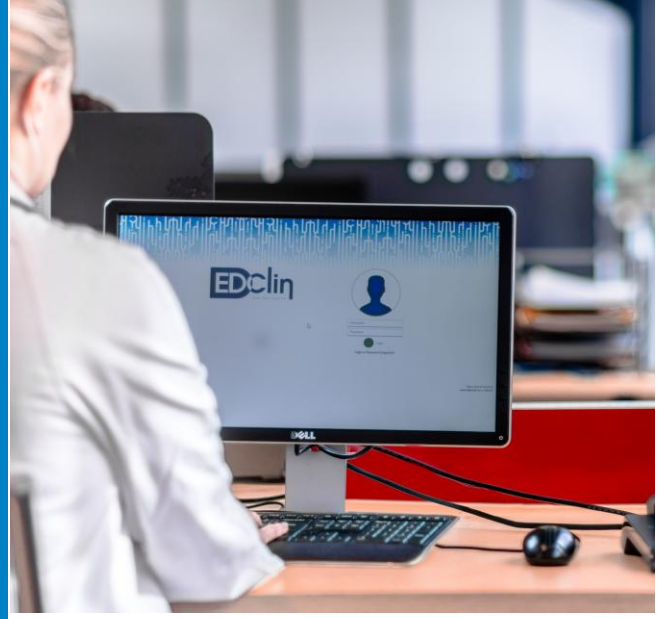

Team

10+ team members including Senior Director IT/IS Master Data Managers, JAVA Developers, IT Administrators, SAS Programmers, IT Engineers and Software Quality Engineer

EDC & Data collection

Our proprietary EDC platform EDClin™ is a Web application complying with 21 CFR/part 11. It is based on Jakarta EE and Oracle database, developed following GCP for Data Management.

→ A simple-to-use interface and query management system.

→ A variety of customizable data access, reporting, and storage options.

→ Clean, error-proof data, immediately available for analysis.

→ Possibilities for remote monitoring & query management.

→ Interactive data capture for patient questionnaires.

→ Options for development of patients' apps on website or application stores.

EDClin
Easy Data Capture

https://www.edclin.com/home
https://www.edclin.com/epro

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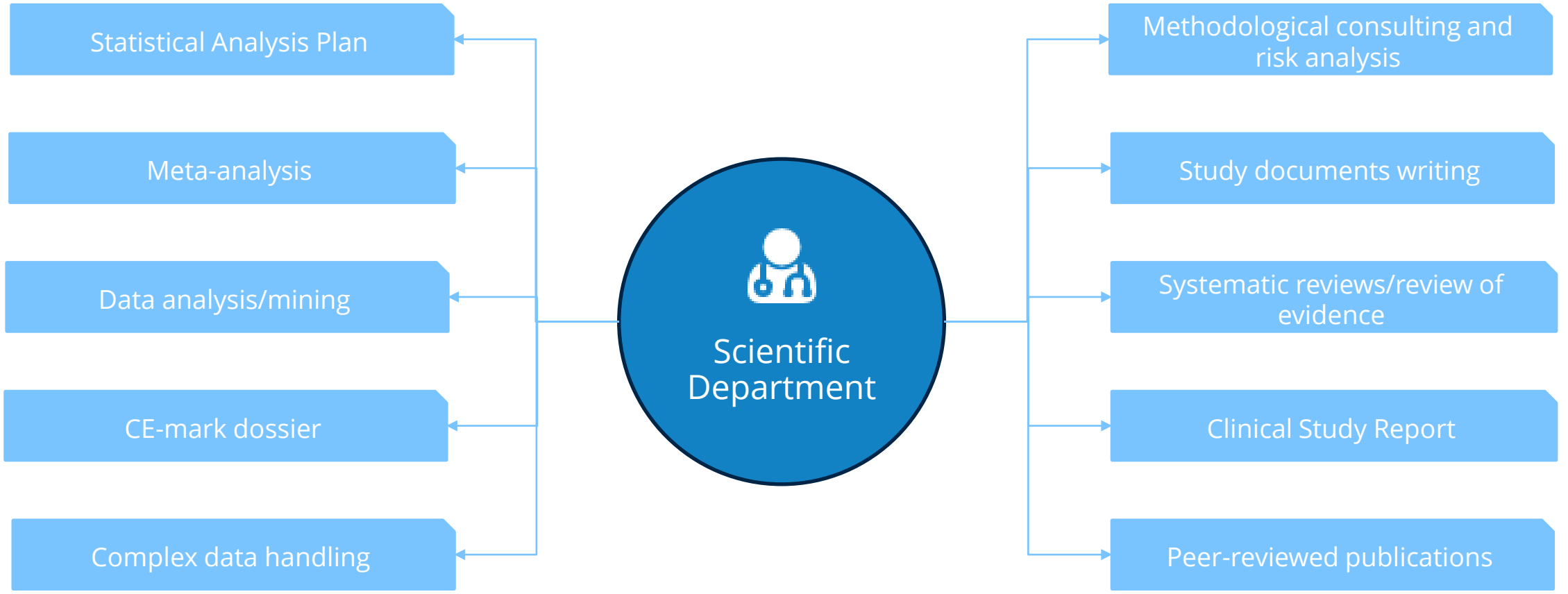
Scientific Advisory team



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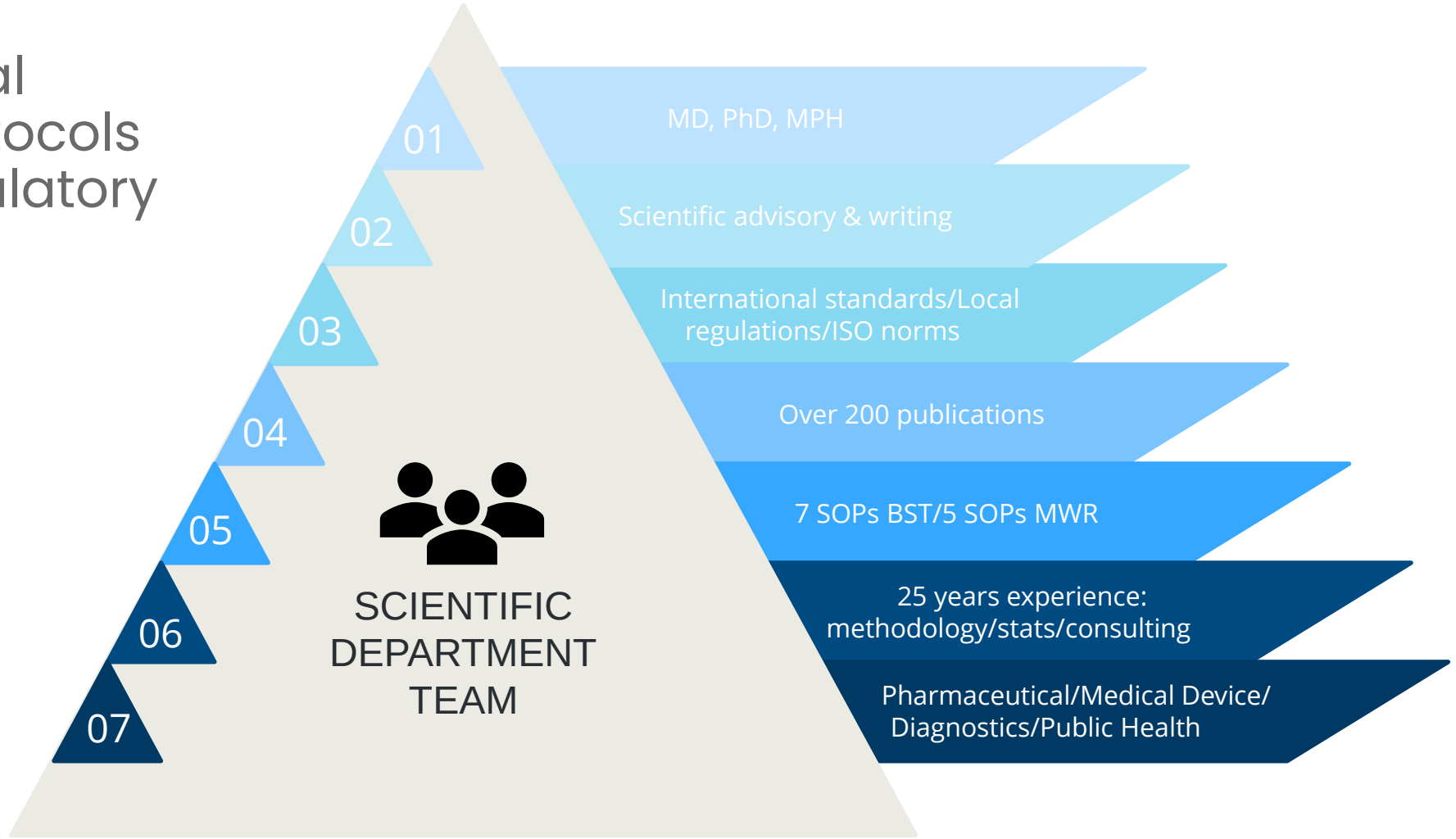
Methodological advice for protocols with clear regulatory roadmaps.



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Therapeutic Care

Hospital prescription

« Thank you for your commitment to us in order to deliver a quality study report.

We will send this final version to the experts for signatures on Monday and attach the report to our HAS filing.

We have an excellent reporting base for the final analysis and congratulations to all the teams because we have exceeded 200 patients included. »

Director of Epidemiological and Medical-Economic Evaluation

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Compassionate and Early Access Programs

Since July 2021

Accès dérogatoire

AAC/AP1/AP2

(CA/EA1/EA2)

~ 1300 patients, majority in oncology

~ 3000 healthcare professionals

~ 500 healthcare institutions

2022 PILOT DGOS-ATIH authentication PASREL

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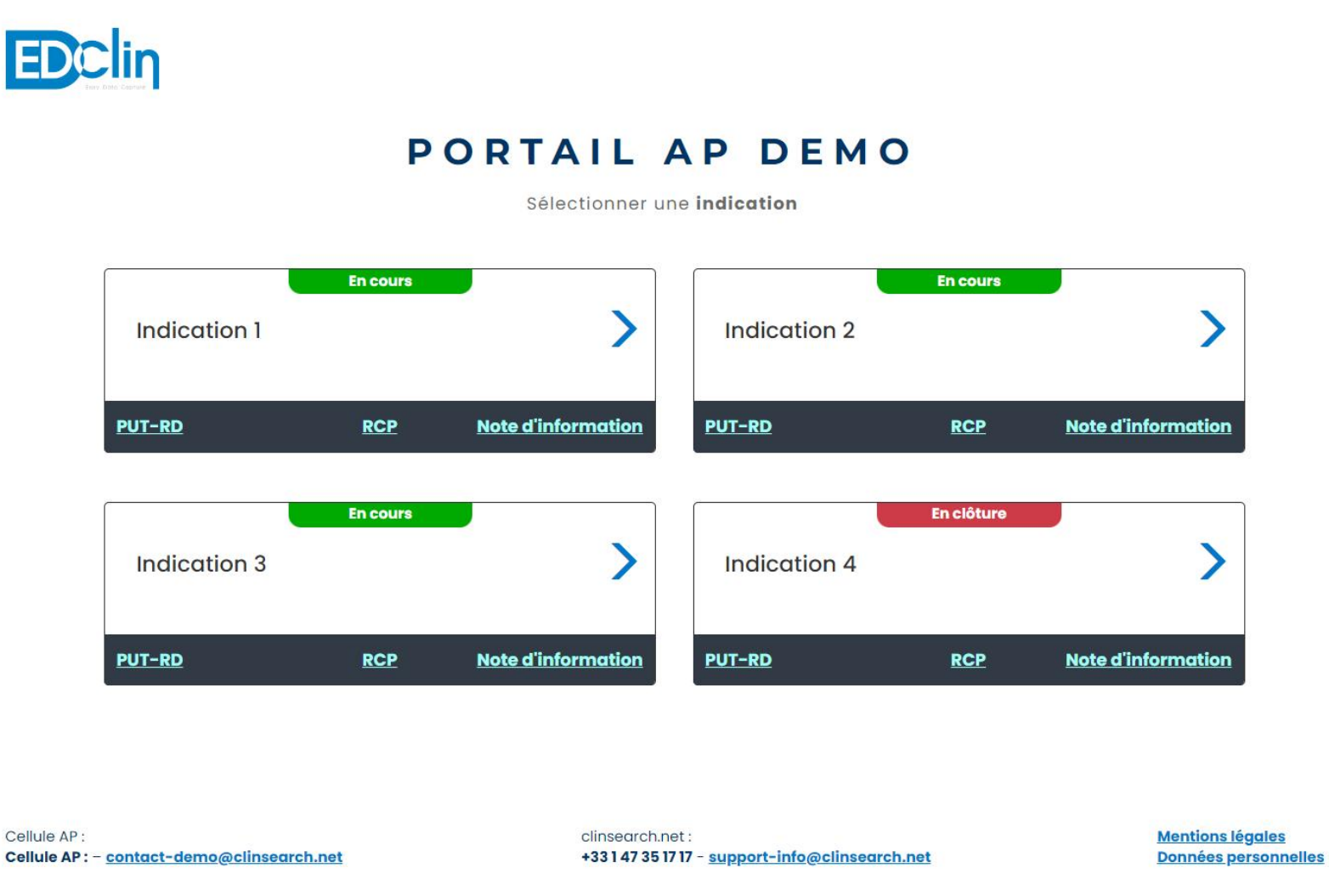
State of the Art Portal

Shared between EA & CA indications

Internally developed & customizable



Once identified, the user navigates without disconnecting from one EA to another by clicking on the tabs of the indications of each EA

Home Page

After connexion

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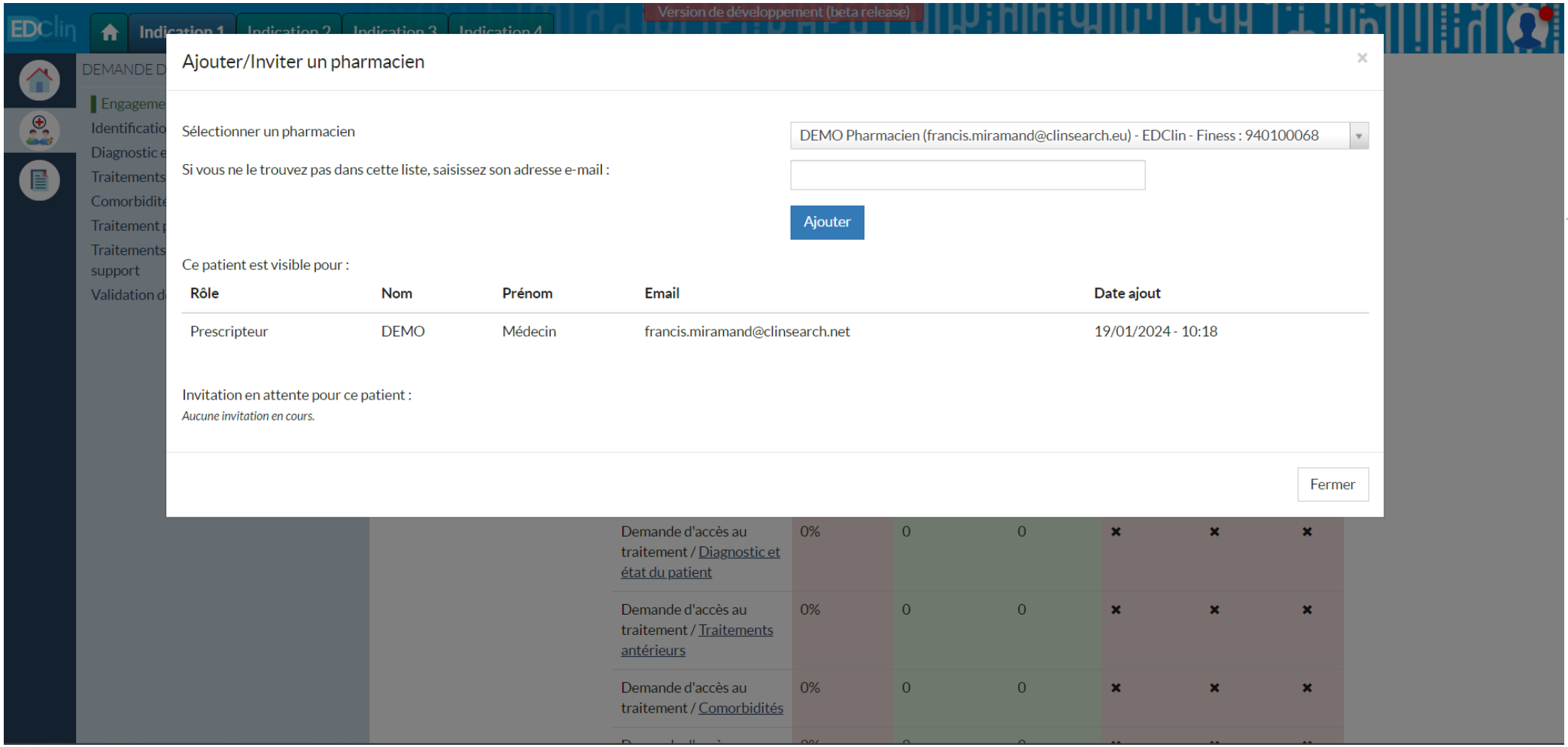
Healthcare professionals can independently give access rights to another healthcare actor to finalize an access request for a patient

Sharing of Patient Record

Invitation of the pharmacist by the prescriber



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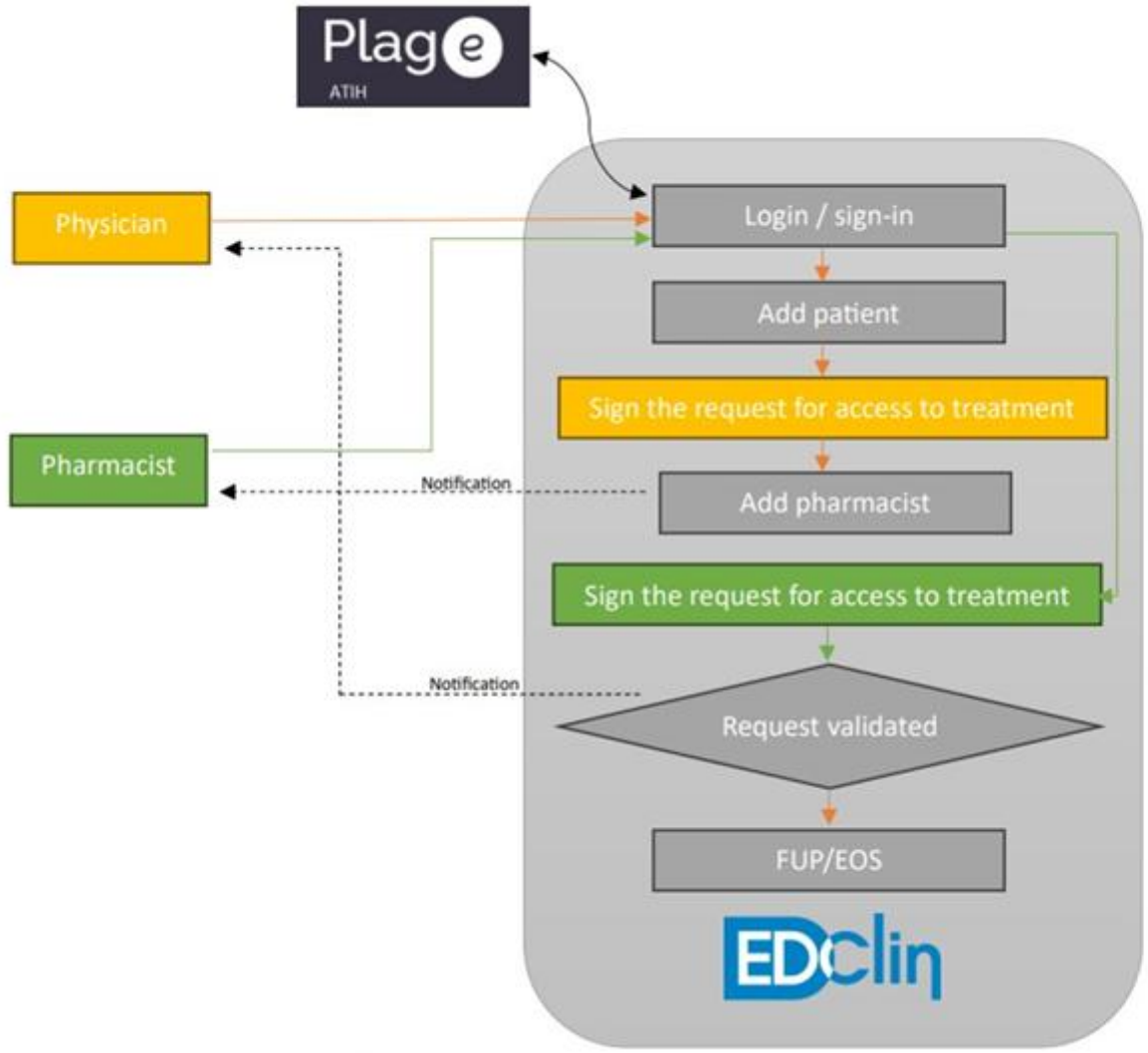
Data Feeds & Hosting

ISO 27001 & « Hébergemer de Données de Santé » (HDS) certified



Note : The starting role can be switched (pharmacist add patient and invites physician).

The EDC system will be hosted on two dedicated servers provided by OVHCloud HDS: a data center located in Roubaix and another in Gravelines, France.

Both data centers are HDS certified as well as ClinSearch.

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PUT DEVELOPMENT

STUDY DOCUMENT DRAFTING

DEVELOPMENT OF ACCESS PROGRAMS AND ASSOCIATED TOOLS SUCH AS EPRO

FULLY AUTOMATED ACCESS REQUEST MANAGEMENT

CONTRACTING WITH SITES/
SITE BILLING AND PAYMENT VIA DEDICATED APPLICATIONS WITH DASHBOARD REPORTING

DATA ANALYSIS AND REPORTS FOR AUTHORITIES

SAP DEVELOPMENT, STATISTICAL PROGRAMMING

PV ACTIVITIES

Project
Management
Treatment
Access
Helpline Support
Remote
Monitoring
Reporting

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Medicine Acceptability

CAST®

ClinSearch Acceptability Score Test

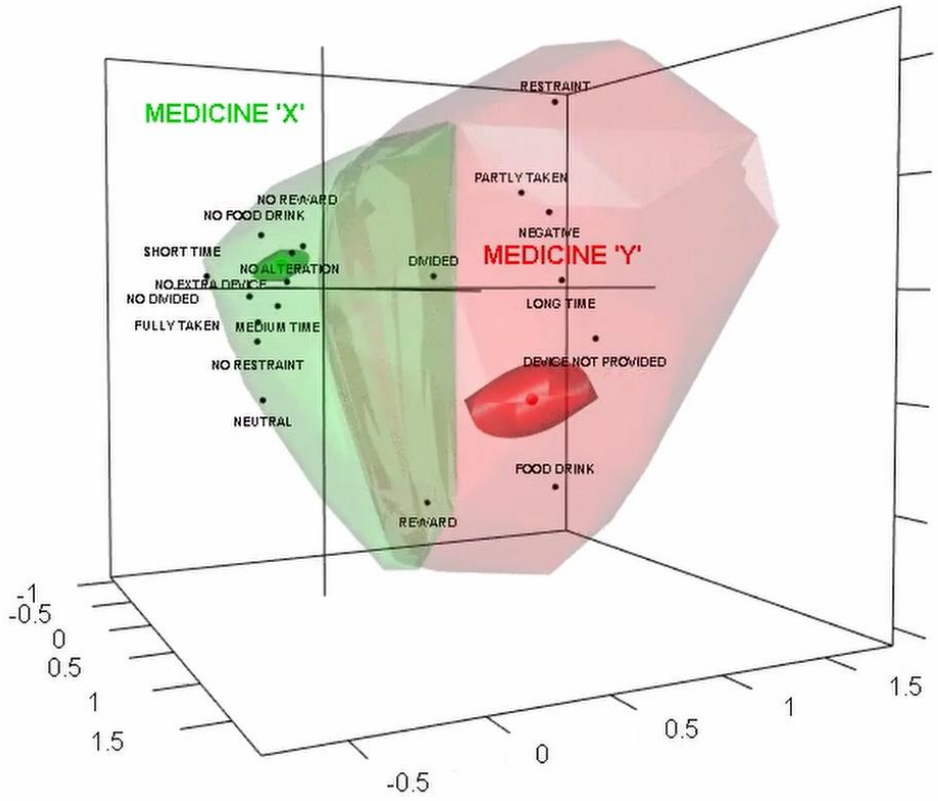
‘the overall ability and willingness of the patient to use and its caregiver to administer the medicine as intended’[1]

[1]European.Medicine.Agency.(EMA) . Guideline on pharmaceutical development of medicines for paediatric use. 2013.

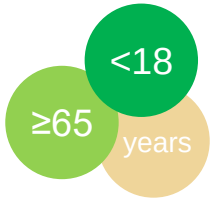
ClinSearch Supporting your innovation

CAST®

Medicine Acceptability Comprehensive Scoring



Questionnaire ***Database*** ***Data Mining*** ***Scoring***



2 versions: pediatrics and older population

>5k standardized evaluations in real life conditions

from France, Poland, Morocco, Japan, India, Peru…

Letter of support issued by the European Medicines Agency (EMA)

referenced in the WHO toolkit for pediatric antiretroviral drugs

15 peer reviewed articles, 3 theses, 17 podiums & 8 awards

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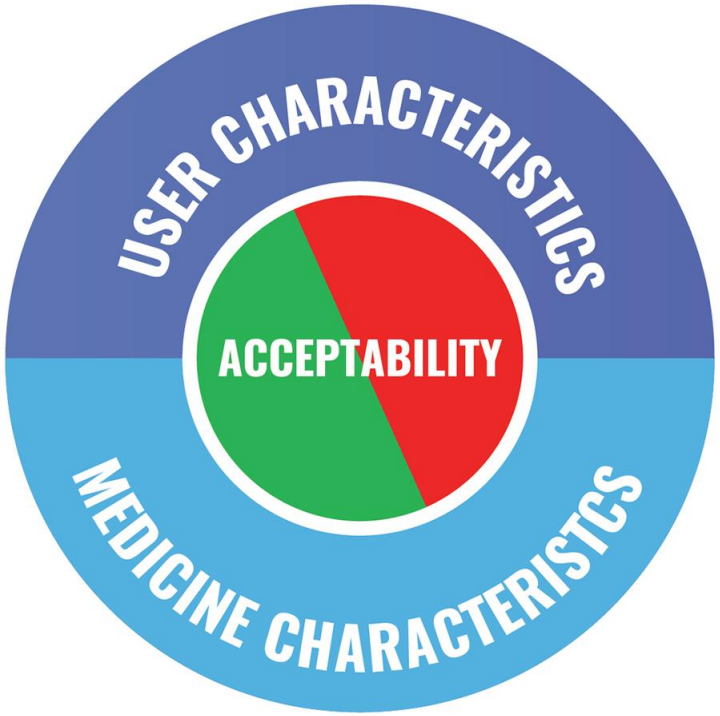
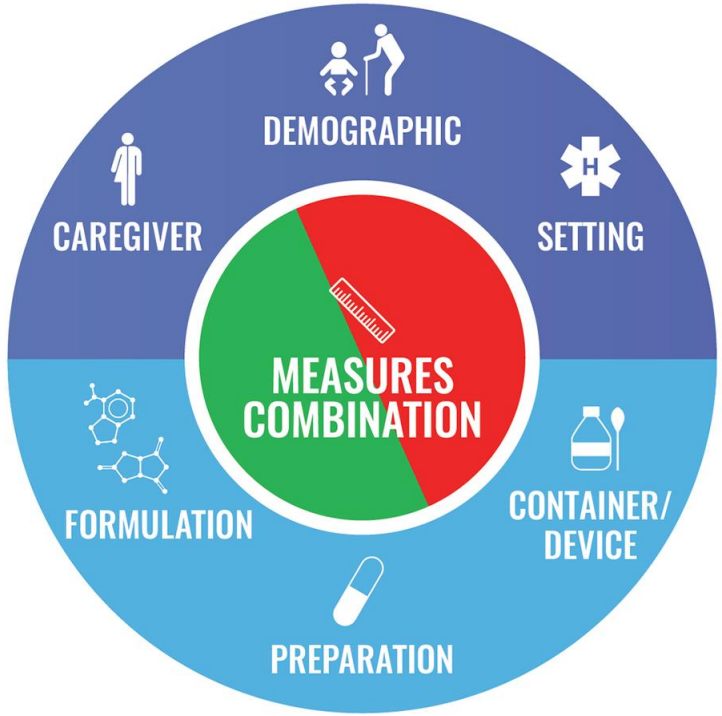
Investigation & Scoring Tool

“Qualification of novel methodologies for drug development”





Ruiz F, et al. (2019) Dosage form suitability in vulnerable populations: A focus on paracetamol acceptability from infants to centenarians. PLoS ONE 14(8)

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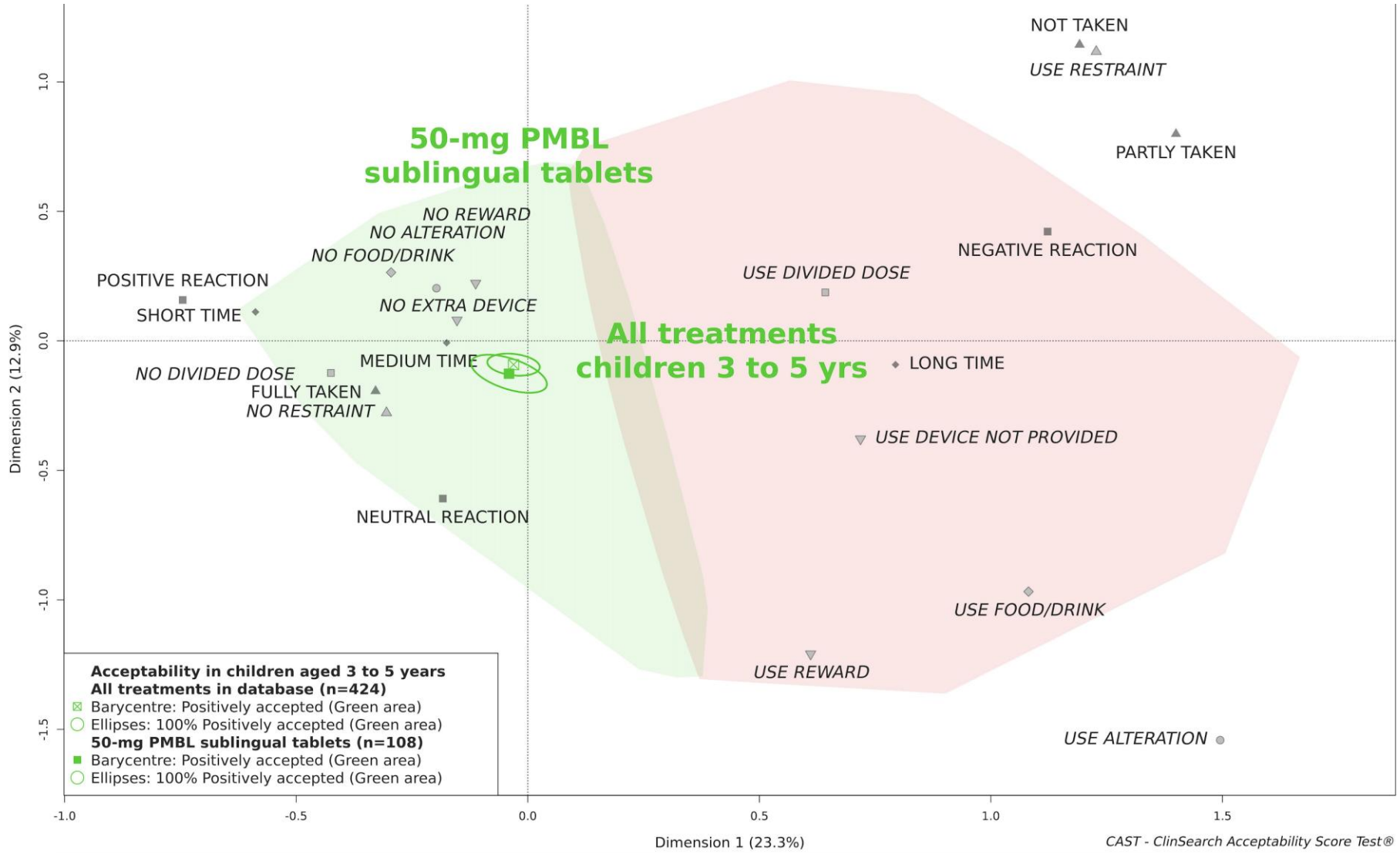
EMA Question



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Emeryk A et al (2021) Acceptability of a Sublingual Drug Formulation for Respiratory Tract Infections in Children Aged 3 to 5 Years. Pharmaceutics.

International Academic & Institutionnel network

- France
- Germany
- United-Kingdom
- Norway
- Poland
- Peru
- Morocco
- India
- Japan

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WHO Recognised

Research Toolkit
Module 5: Acceptability

TOOLKIT FOR RESEARCH AND DEVELOPMENT OF PAEDIATRIC ANTIRETROVIRAL DRUGS AND FORMULATIONS

WHO and UNITAID
in collaboration with IMPAACT (International Maternal Pediatric Adolescent AIDS Clinical Trials) network, PENTA (Paediatric European Network for Treatment of AIDS) foundation and experts from the Paediatric Antiretroviral Working Group

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 Febraury 2023
EMADOC-1700519818-1066960
Executive Director

EMA
LoS

"Qualification of novel methodologies for drug development"

38th since 2007

Letter of Support for an Acceptability Score Test in relative acceptability testing for oral medicines in children under 12 years of age

On 10/03/2022, the Applicant Clinsearch requested a follow up qualification advice for their Acceptability Score Test pursuant to Article 57(1)(n) of Regulation (EC) 726/2004 of the European Parliament and of the Council. On 12/01/2023, the SAWP agreed on the advice to be given to the Applicant. On 26/01/2023, the CHMP adopted the advice to be given to the Applicant.

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ClinSearch
Supporting your innovation

COHORTS
Prevalence of Target Population & Burden of Disease

Primary data + secondary data

National Cohort Study

Prevalence & Burden

Context

J_0	Product in phase III
$J_{0\ +20\ months}$	AMM + CT File

Goals

Determine the patient profile of the target population in terms of prevalence, socio-demographic characteristics, quality of life and consumption of healthcare and associated costs.

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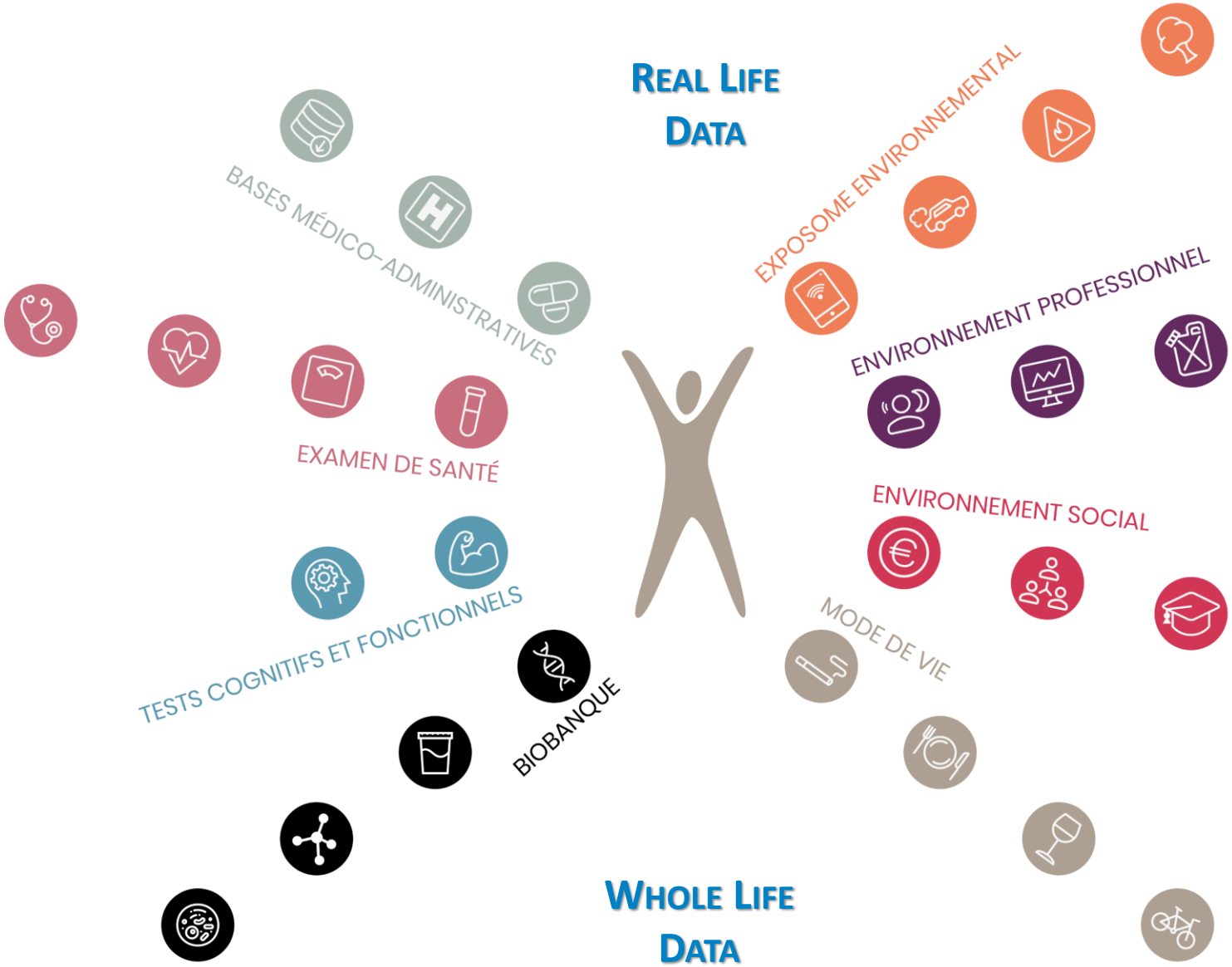
Cohort CONSTANCES

Epidemiological cohort of 220,000 adults in France



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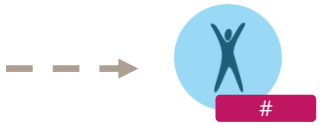
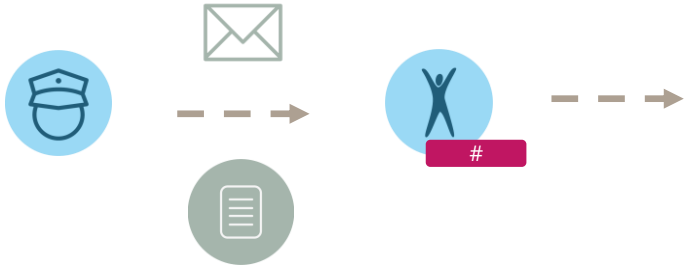
Selection criteria of the target population in the cohort



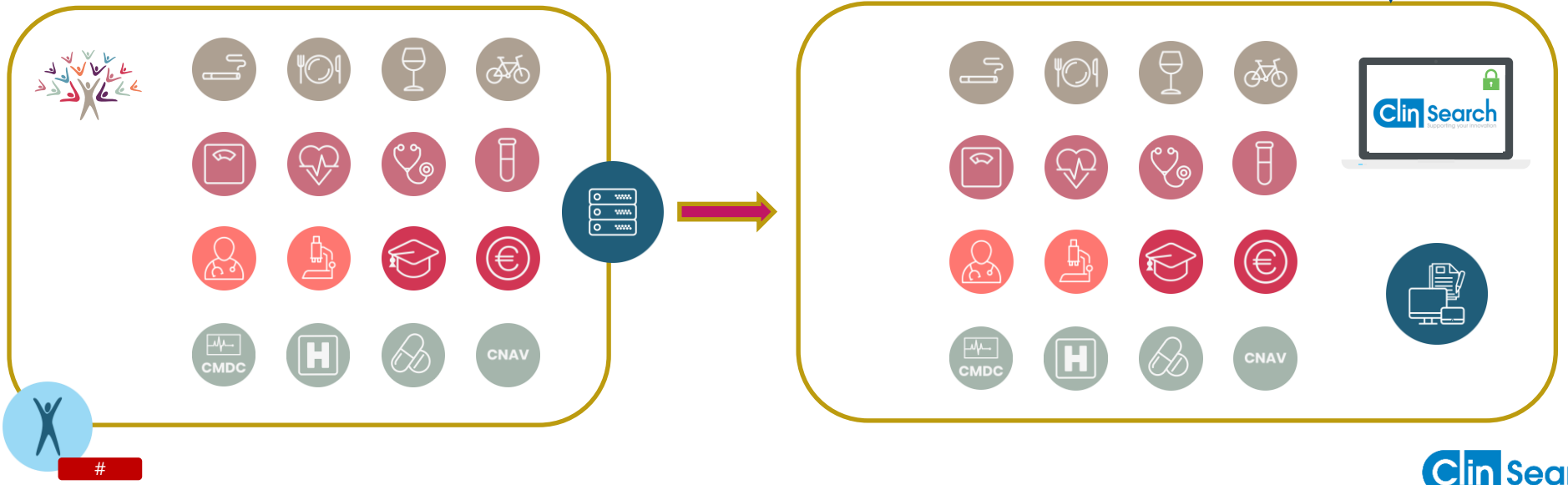
Selection of subjects
1 case / 1 control
paired



Ad-hoc Questionnaire

Ad-hoc Study

Data Generation Flowchart



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ClinSearch

Legifrance.gouv.fr
LE SERVICE PUBLIC DE LA DIFFUSION DU DROIT

JORF n°0071 du 24 mars 2017
texte n° 28

Arrêté du 22 mars 2017 relatif au référentiel de sécurité applicable au Système national des données de santé

10. Homologation

Avant la mise en œuvre du système, celui-ci doit faire l'objet d'une homologation formelle par le responsable de traitement (i.e : acceptation des risques résiduels).

IS Security

Approval

a Sopra Steria company

VISA DE SÉCURITÉ

INTERNAL

EXTERNAL

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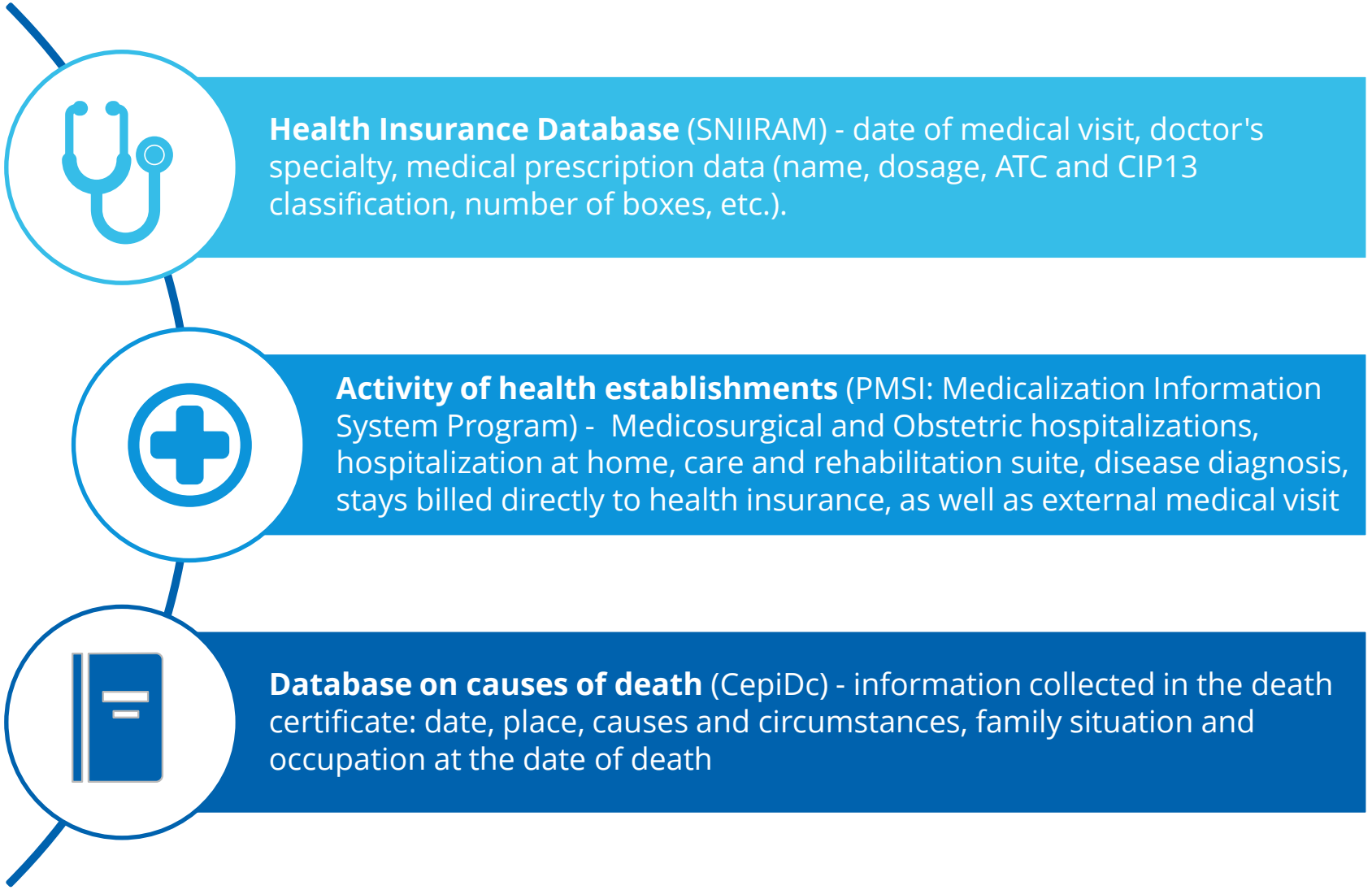
SNDS Pairing

SNDS: National health data system

Système National des Données de Santé



Health Insurance Database (SNIIRAM) - date of medical visit, doctor's specialty, medical prescription data (name, dosage, ATC and CIP13 classification, number of boxes, etc.).

Activity of health establishments (PMSI: Medicalization Information System Program) - Medicosurgical and Obstetric hospitalizations, hospitalization at home, care and rehabilitation suite, disease diagnosis, stays billed directly to health insurance, as well as external medical visit

Database on causes of death (CepiDc) - information collected in the death certificate: date, place, causes and circumstances, family situation and occupation at the date of death

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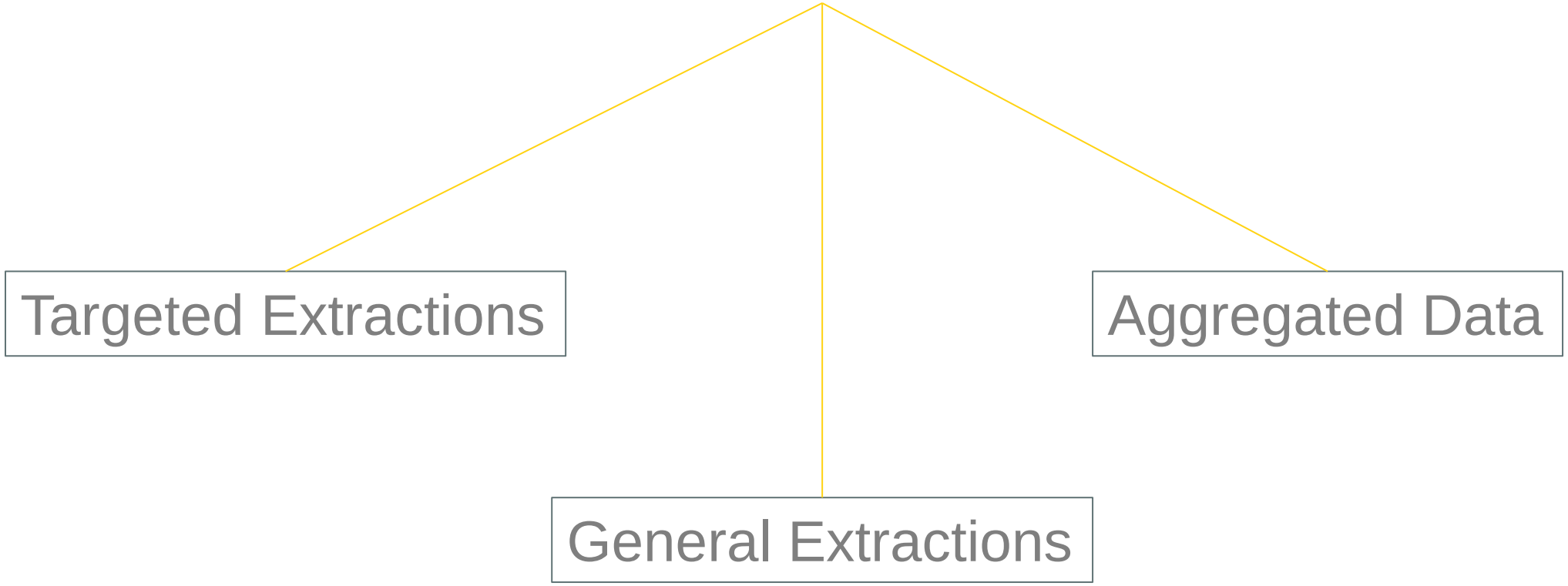
Authorization to work on data from

SNDS
Système national des données de santé

7 staff members As of 31/12/2023



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Customer Satisfaction

95% of our surveyed clients are *Very Satisfied* or *Satisfied* with:

- Our knowledge, availability and advice
- Project management, and quality
- Communication with Project Leader

Client satisfaction survey 2023

"ClinSearch is a great partner to work with, with every team member being professional and efficient. They have a truly proactive approach and propose actions when they foresee any risks. They are reliable and committed to the established agreement. The ClinSearch team is very focused on what we ask them to do and excel at prioritizing." Clinical Programs Manager, Medical Device Multinational-France

"ClinSearch is a top-notch organization. The team I have worked with is extremely skilled, accountable for their work, and easy to work with. Whenever there is a question or issue that needs to be addressed, I know that it will be taken care of in an expedited manner. The organization is a real pleasure to work and do business with." Director, Clinical Operations, Start-up-USA

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ISO 27001

ISO 27701

Audit Q1 2024

Since 2012

NUMÉRIQUE LNE CERTIFICATION HDS

Accompaniment

OWN SECURITY

VISA DE SÉCURITÉ

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