CRO Charité Research Organisation

scientifically driven

Charité Research Organisation

Our Concept

CRO Charité Research Organisation

Charité Research Organisation

Charité owned | operationally independent | scientifically driven

Qualified Phase 1 and POC unit

30 beds (expanding to 70 in early 2018) with an additional out-patient facility. Access to patients, clinical expertise, biomarker, imaging and diagnostic capabilities. Independent subsidiary of Charité – Universitätsmedizin Berlin.

Staffing

Approximately 150 dedicated staff, including board certified physicians, nurses, lab technicians, pharmacists, PMs, QMs, data entry staff and independent QA.

Experience

Conducted more than 300 First Time in Human, Phase 1 and POC projects since launch in 2006. Pioneered FTIH and Phase 1 studies in patients.

Key research areas

Rheumatology, dermatology, gastroenterology, endocrinology, pulmonology, cardiology, neurology, psychiatry, infectious diseases, ophthalmology, oncology.

Study types

First Time in Human, Phase 1, POC. Includes biosimilar studies, imaging and methodology studies, blood and tissue sampling studies, pre-screening studies.

Access to accredited safety lab, ISO certified biomarker labs, imaging facilities and licensed GMP pharmacy.

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CRO can provide a full service

Internalised

- Scientific & Regulatory Consultancy
- Project Management
- Protocol Development
- Ethical & Regulatory Submissions
- Clinical Conduct
- Medical Writing

Partnered
(University or external)

- Routine Laboratory Analysis
- Biomarker Validation & Analysis
- GMP Pharmacy
- Monitoring
- Data Management
- Statistical Analysis

Overseen by an ICH-GCP compliant QA / QM system

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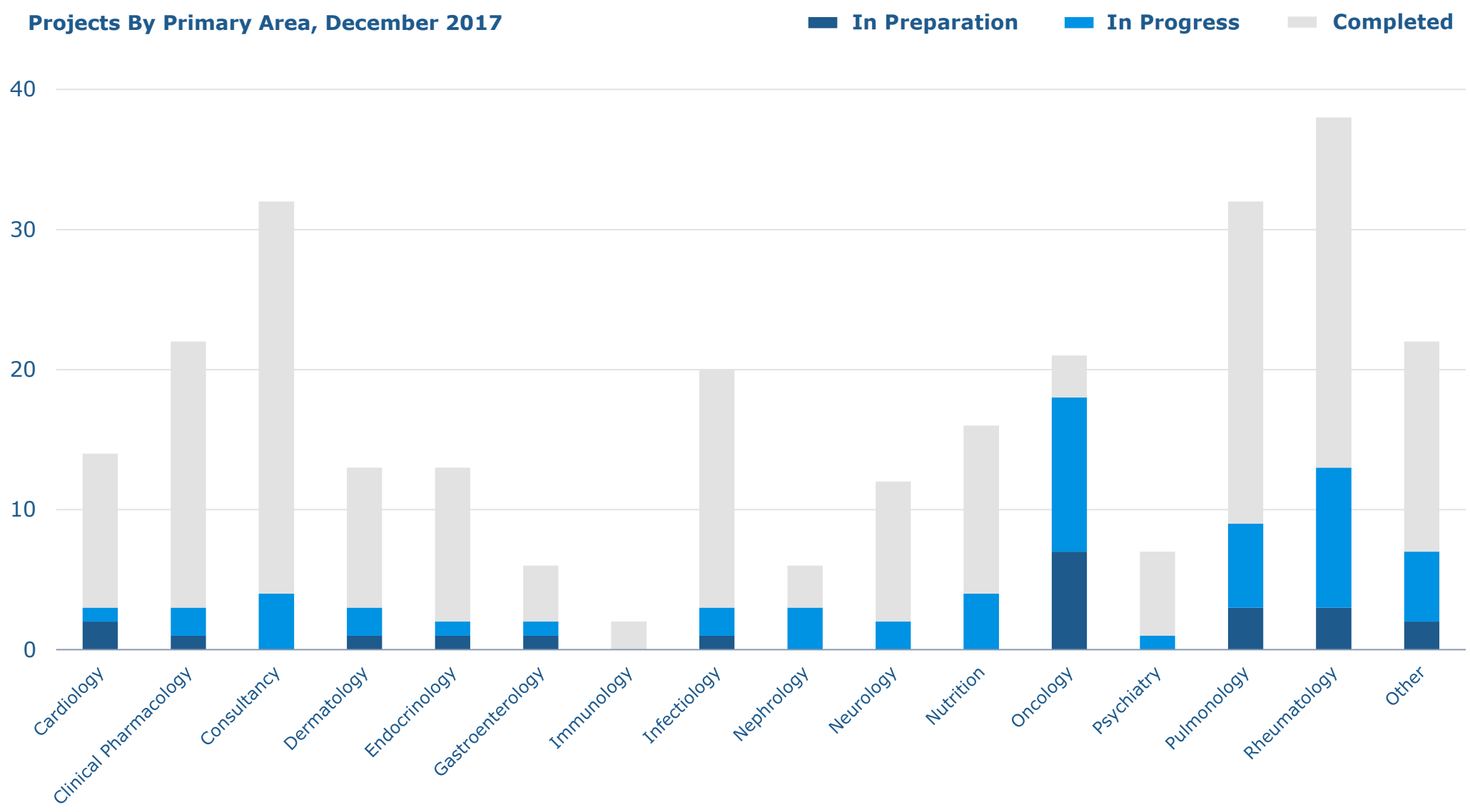
330 FTIH-PoC Projects to date

From more than 50 industry sponsors



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FTIH-POC Success Stories

Phase I in HV and Crohn's Patients

- SAD study in n=64 HV patients & n=24 Crohn's patients
- Completed with a single centre approach

Phase I in Moderate-Severe Psoriasis Patients

- Multiple dose interaction study in n=21 moderate-severe psoriasis patients
- German-wide recruitment and enrolment completed in approx. 4 months
- Completed with single centre approach

FTIH in RA Patients

- Study in n=92 RA patients across SAD i.v., SAD s.c. and MAD s.c. parts with imaging and biomarkers analysed locally
- Completed with a single centre approach

Phase I in HVs and Asthma Patients

- Study with n=80 HVs across MAD and FE parts and n=54 mild-moderate asthma patients enrolled in approx. 2 months
- Completed with a single centre approach

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Recruitment Case Study

Phase I Psoriasis

Study Population

Psoriasis

Area
Dermatology

Assessments
PASI, psoriasis target lesion score

Recruitment Strategy
Database & online marketing

Single-Centre
n=61 psoriasis patients in 6 groups

Study Duration
4 weeks SCR
12 to 17 weeks treatment + FUP

Total Enrolment Duration
Approximately 8 months of active enrolment across all groups

Screened	Randomised	Completed
156	61	58

3 drop-outs

- 40 out of 61 patients [66%] randomized with a PASI score of 4 or higher on Day -1
- Average PASI score of 8,3 on Day -1 for randomised patients
- Average recruitment rate of 8 per month

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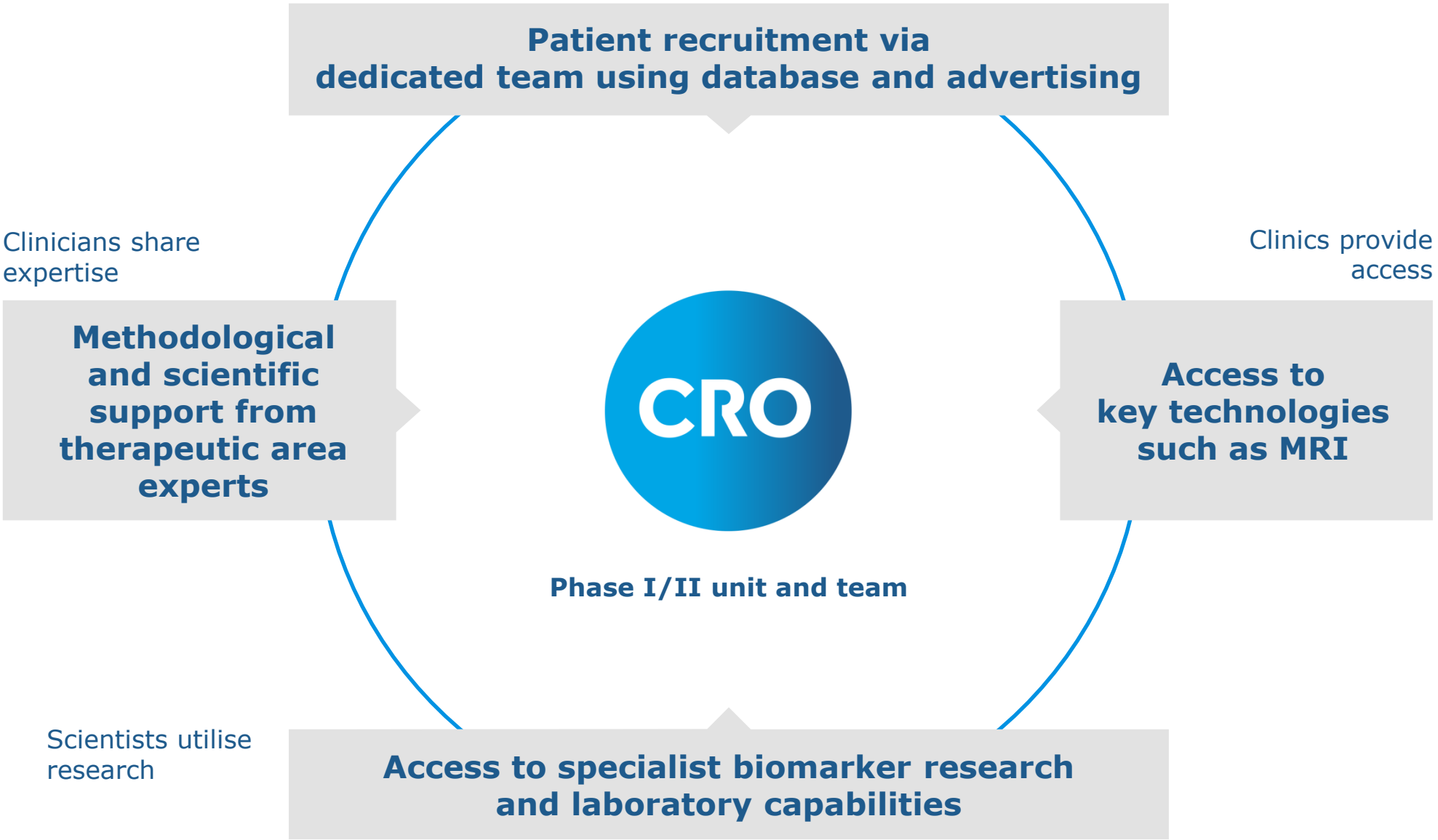
CRO Centres of Excellence Approach



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CRO Centres of Excellence

Clinical and scientific support across multiple disciplines

Key examples include dermatology and rheumatology

Prof. Dr. med.
Gerd Burmester

Prof. Dr. med. Gerd Burmester

Imaging with central scoring services: MRI, US, FOI, X-Ray, CT, PET

Prof. Dr. med.
Marina Backhaus

PD Dr. med.
Kay-Geert Hermann

PD Dr. med. Kay-Geert Hermann

ISO certified Immunological Study Laboratory (ISL)

Off the shelf assays, transfer and validation of sponsor assays, research laboratory

Prof. Dr. med.
Hans-Dieter Volk

PD Dr. Gerald Grütz

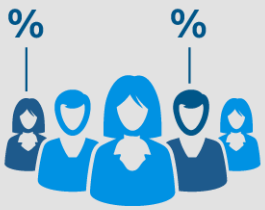
Prof. Dr. med. Hans-Dieter Volk

Feasibility Process

Determining the number of potentially eligible subjects

Prevalence

What is the general indication specific prevalence?



- Prevalence of rheumatoid arthritis: approximately 0.5%

Subset of Population

Based on the prevalence what is the subset of the Berlin/German population we can target?

- Population of Berlin/Germany: 3.5/81 million
- RA patients in Berlin/Germany: 3.5/81 million x 0.5% = 17,500/405,000

Potentially Eligible Subjects

Based on experts' judgement what percentage of this subset is represented by the defined inclusion/exclusion criteria?

- Percentage of RA patients represented by inc./exc. criteria: 30% (for example)
- Potentially eligible RA patients
- in Berlin/Germany: 17,500/405,000 x 30% = 5,250/121,500

CRO Recruitment Approach

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Appeal directly to the patient + **Have the resources to treat the patient with utmost respect** + **Financially compensate the patient appropriately**

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Innovation: A National Single Centre

One centre | German-wide Sjögren Patient Recruitment

11 patients from Berlin
16 from the rest of Germany

European Clinical Research Review | S. Gadola, S. Oliver |
25 May 2015 VAY736 in RA, pSS and PV

250 telephone contacts

100 information sessions

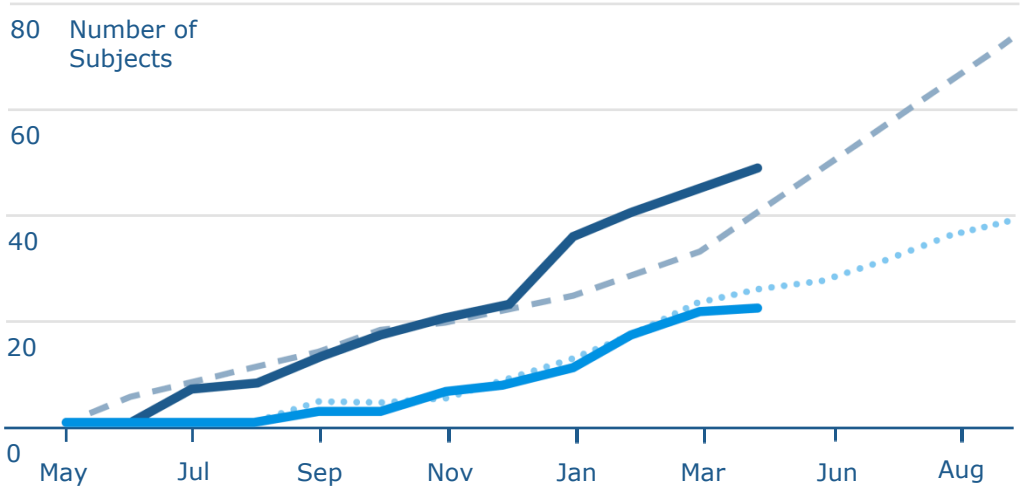
54 screenings

21 Google

6 Referral

27 enrolled patients

Study VAY736X2201 recruitment



Innovation: Pre-Screening Studies

Pre-screening study approved by local ethics	**n=244 asthma patients identified and pre-screened against key study inc./exc. criteria before and during conduct of HV part**
Core block of patients identified to push to main study	**n=108 considered to be "probably" eligible for main study**
Ultimately n=98 retained for main study screening	**n=98 entered into main study screening**
n=54 randomised	**n=54 randomised in just over 2 months in 2 parallel cohorts of 27**

CRO Centres of Excellence

"Working with Charité Research Organisation allows me to contribute both scientifically and practically. We have been able to incorporate innovative MRI imaging techniques in early phase RA studies – such as Dynamic Contrast Enhanced MRI – and also explore the potential for MRI to be utilised in other indications such as OA and SpA."

PD Dr. med. Kay-Geert Hermann
Charité Radiology Institute

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