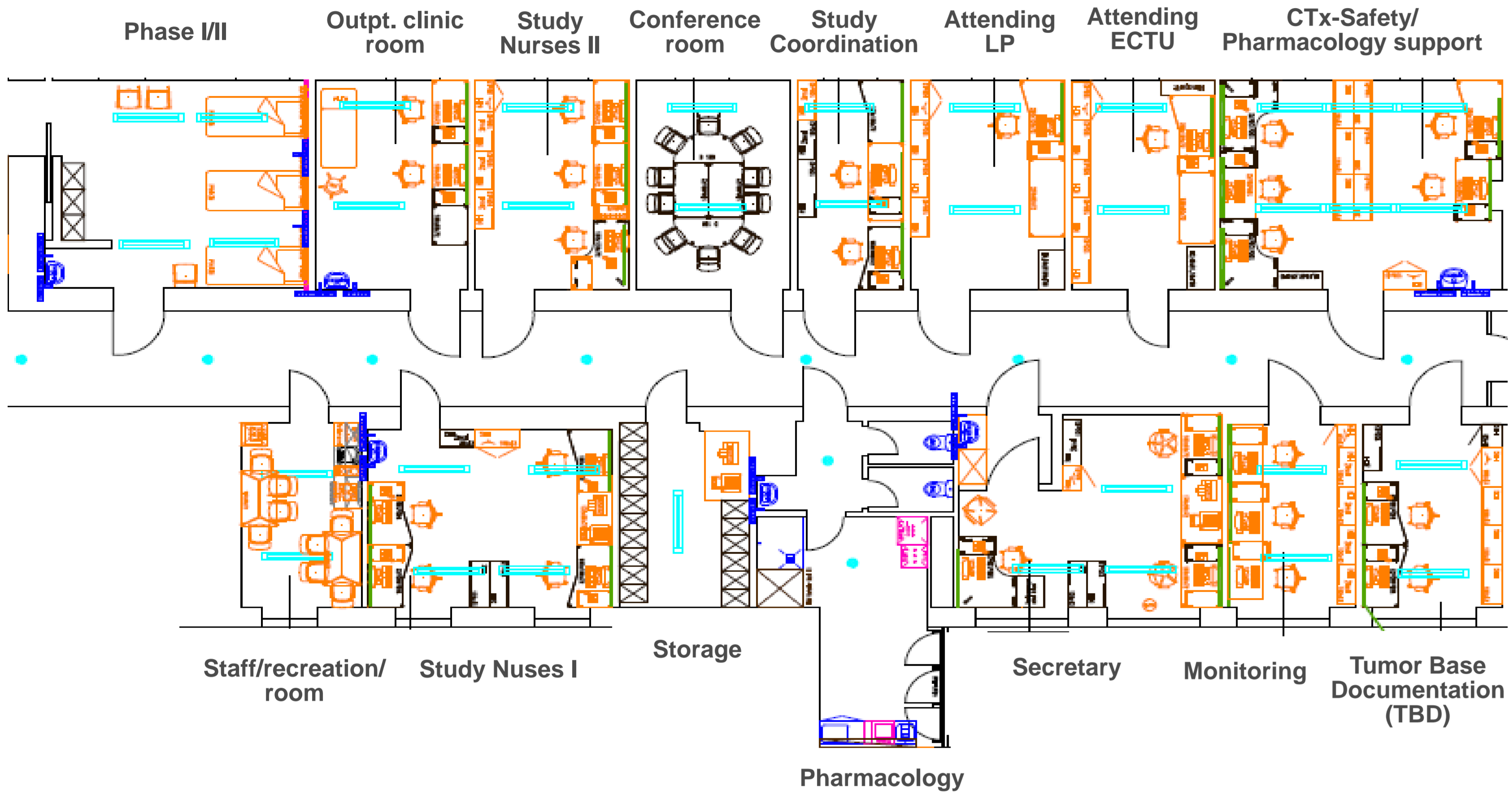


CCCF - Early Clinical Trial Unit (ECTU)

M. Möller, L. Illert, A. Krohn, C. Kiote-Schmidt, U. Kohlweyer, F. Haug, M. Falahen, C. Messner, J. Meisenzahl, D. Jakobs, M. Linder, S. Kappes, I. Surlan, M. Höfflin, H. Fricker, H. Reinhardt, S. Kaiser, M. Szymaniak-Vits, P. Otte, H. Schall, J. Urban, S. Demmig, S. Wenske, R. Lohmüller, R. Wäsch, R. Bredenkamp, J. Duyster, M. Engelhardt

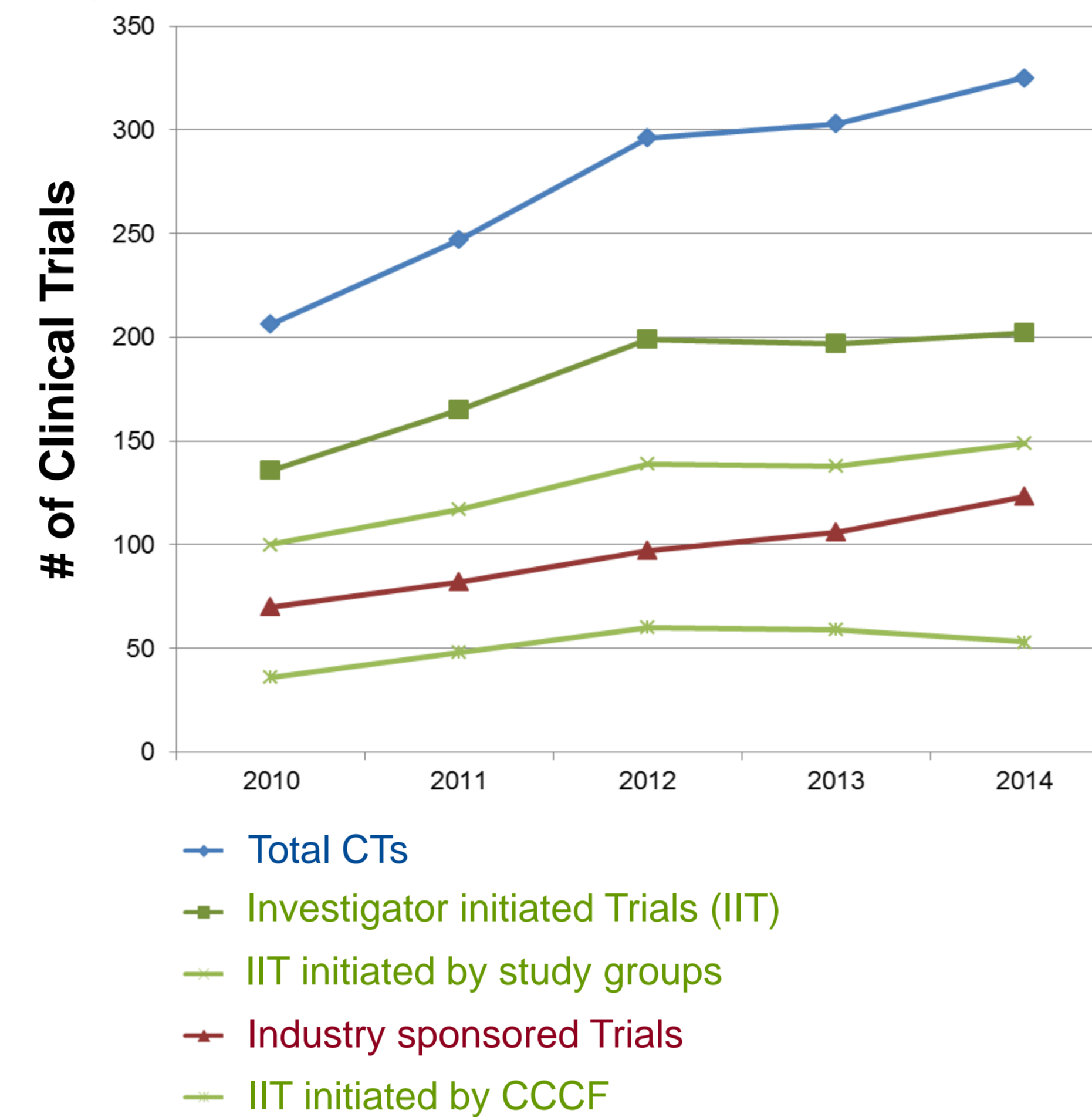


Site map ECTU + Clinical Cancer Research Group (CCRG)



Clinical Trials University Medical Center Freiburg (UKF)

of ongoing CTs_{CCCF/UKF}



Currently performed phase I/II CTs_{CCCF/UKF}

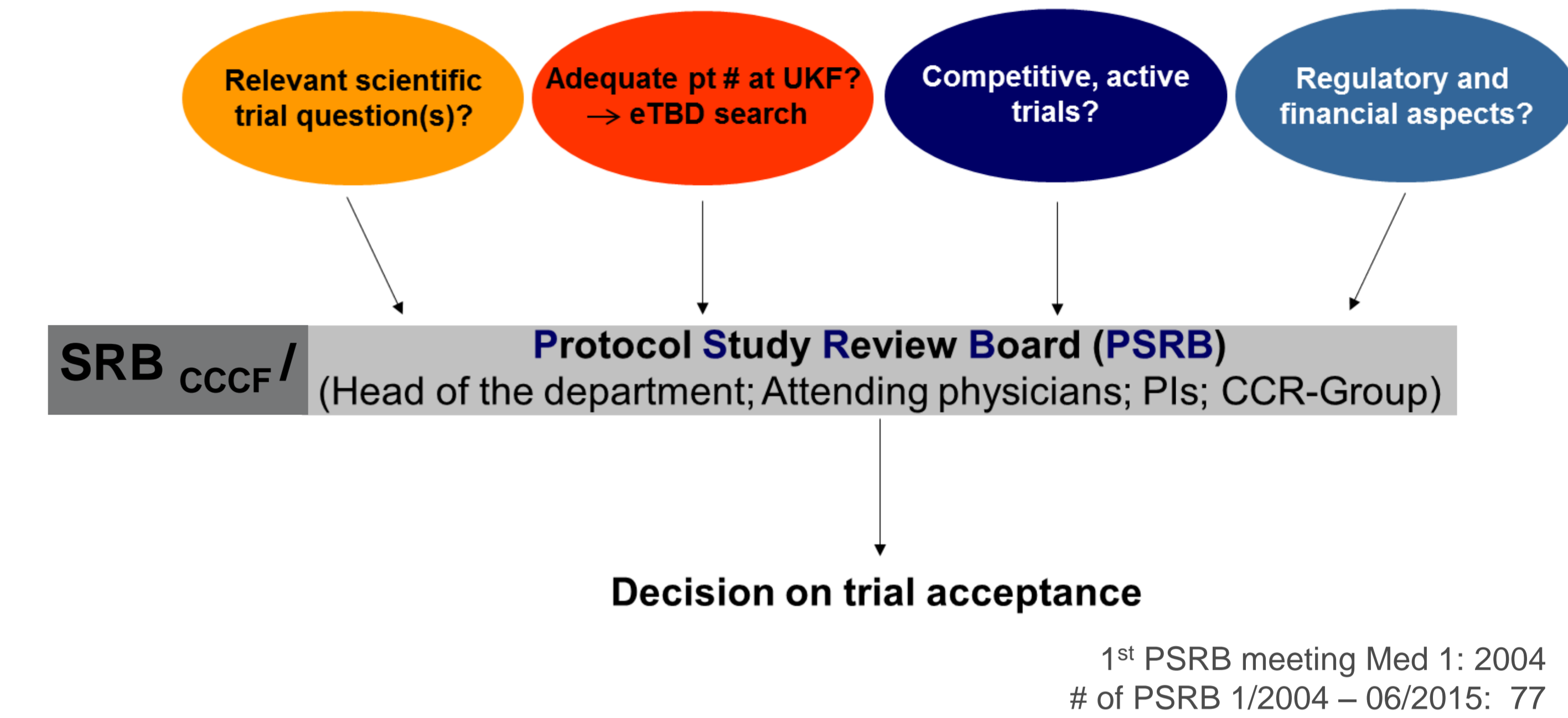
Clinic	UKF
Hematology & Oncology, Med. I	19
Gastroenterology, Med. II	2
ZKJ	4
Urology	1
Neurology	1
Total	27

Early Clinical Trials at Department of Hematology & Oncology

of CTs, included pts and pt-#/CT at Med I₂₀₁₄

	Phase I, I/II	Phase II	Phase III	Other	Σ
# of CTs	19	35	46	19	119
# of pts	78	256	226	1018	1578
Pt-# / CT	4.2	7.3	4.9	53.6	13.3

Trial discussion and acceptance modus



Realized structures for phase I+II clinical trials (CTs)

- 6 beds (3 outpt care in ECTU, 3 inpt beds ward 'Holthusen')
 - SN support, study coordination, monitoring, CTx-management, pharmacology, TBD: all integrated in new ECTU unit
 - Medical equipment all available (monitors, infusion pumps, ECG, emergency equipment)
 - CT-specific equipment in place (centrifuges, refrigerators, study medication storage room, monitoring + study audit capacities)
 - Combined organization of phase I/II + Leucapheresis (LP) + CCR-Group to personnel-efficient unit
 - Proximity to leukemia ward (24h-physician support)
 - Central location + easy access to intensive care unit
- **Central unit for all oncology-active departments for proficient ECTU performance**

Staffing ECTU/LP/Med I team

Present personnel structure ECTU/LP/Med I:	Phase I/II core team:	Total study team Med 1:
• Senior physicians	■ ■ ■	15
• GCP-approved physicians	■ ■ ■ ■ ■	40
• Study Nurses	■ ■ ■ ■ ■ ■ ■	7
• TBD	■	2
• Study coordination	■ ■ ■	3
• Pharmacists (CTx-management / study support)	■ ■	3
• MTA	■	1
• Biometry	■ ■	2
• PhD position (Pharmacist)	■	1
• Secretary	■	1

Opportunities and prospects of ECTU

- As central unit, the ECTU allows translational research and further improves oncology investigations for UKF
- Logistic and structural requirements for expertise performance of early CTs with GCP-approved personnel for outpts and inpts
- Enables all oncology-active departments within interdisciplinary platform to perform phase I+II CTs
- Fulfills all requirements for phase I +II CTs, also as a proficient partner for pharmaceutical companies*
- Is integral part of the CCCF and directed in close collaboration with CCCF associated members
- Head of Trial Unit: Prof. Dr. M. Engelhardt
- Section Haematology: FOA Dr. L. Illert
- Section Oncology: A. Krohn

* Industry cooperations:

Novartis: OTM certification 8/2014
 Roche: in preparation
 Bayer: in dialogue
 Preferred partner Quintiles since 10/2013
 Preferred partner, preclinical collaborations: Oncotest;
 Prof. Fiebig / Dr. J. Schüler