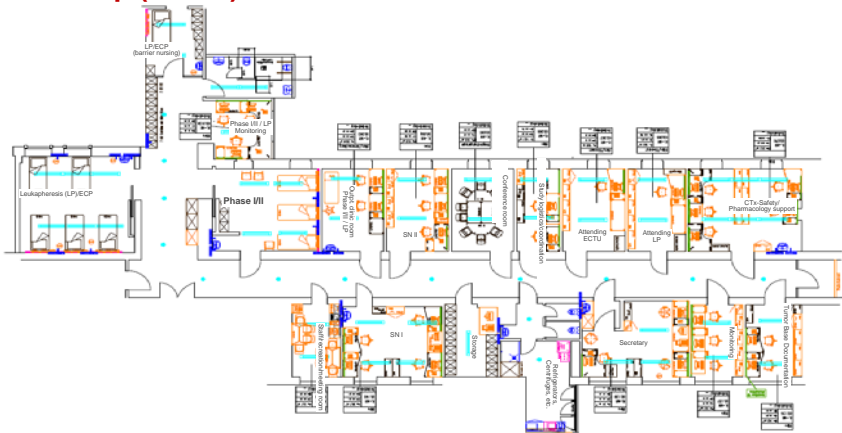


CCCF - Early Clinical Trial Unit (ECTU)

M. Engelhardt, M. Kleber, U. Kohlweyer, R. Bredenkamp, J. Duyster

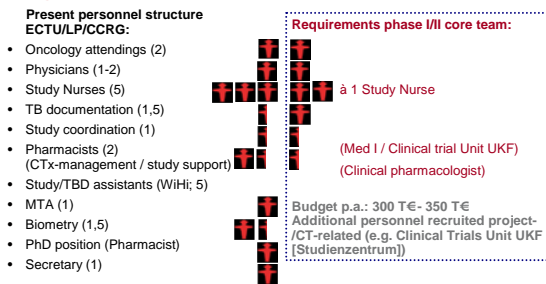
Site map ECTU, Leukapheresis (LP) + Clinical Cancer Research Group (CCRG)



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

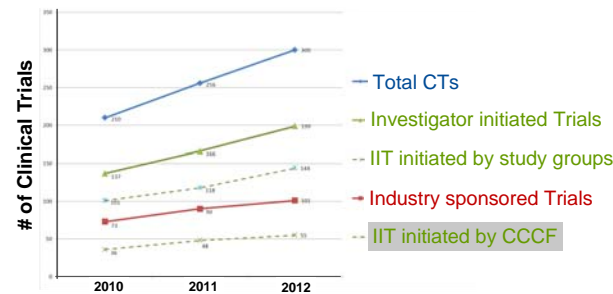
- 8 beds (3 outpt care in ECTU, 3-5 inpt beds ward 'Holthusen')
 - SN support, study coordination, monitoring, CTx-management, pharmacology, TBD: all integrated in new ECTU unit
 - Medical equipment all available (monitors, infusion pumps, ECG, emergency equipment)
 - CT-specific equipment in place (centrifuges, refrigerators, study medication storage room, monitoring + study audit capacities)
 - Combined organization of phase I/II + 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/CCRG team



Results Freiburg Clinical Trials_{CCCF/UKF}

of ongoing CTs_{CCCF/UKF}



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

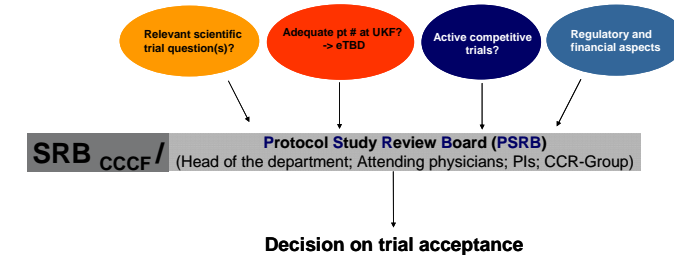
Clinic	UKF
Hematology & Oncology, Med. I	10*
Gastroenterology, Med. II	6
Pediatric Hematology&Oncology	6
Thoracic surgery	2
Ophthalmology	2
Infectious diseases	1
Nuclear medicine	1
Gynecology	1
Radiation Therapy	1
Neurology	1
Total	31

Early Clinical Trials Med 1 (CTs)

of CTs, included pts and pt-#/CT₂₀₁₂

	Phase I, /II	Phase II	Phase III	Other	Σ
# of CTs	10*	26	28	14	78
# of included pts	10	105	28	114	257
Pt-# / CT	1.0	4.0	1.0	8.1	3.3

Trial discussion and acceptance modus



1. PSRB meeting Med 1: 2004
of PSRB 1/2004 - 10/2012: 58

Opportunities and prospects of ECTU

- As central unit, ECTU allows translational research and further improves oncology investigations for UKF
- Logistic and structural requirements for expertise performance of early CTs with study-knowledgeable 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

* Industry cooperations:

Novartis: OTM certification 1/2013
Roche: in dialoge
Preferred partner Quintiles
Preferred partner, preclinical collaborations: Oncotest;
Prof. Fiebig / Dr. J. Schüler