Clinical trials (CTs) and Early Clinical Trial Unit (ECTU) activities within the hematology-oncology department supported by the Clinical Cancer Research (CCR)-Group Freiburg

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I. Background: Tasks and responsibilities CCR

1. **CT coordination in the Dept. of Internal Med. I**
   a) regulatory and financial aspects
   b) CT initiation and assistance (study nurses)
2. **Documentation of all treated tumor patients (CARAT+)**
   data set set-ups, data acquisition/analysis, project management, CT decisions, 'outcome research' questions
3. **Quality control of all given CTx**
   Implementation and updating of:
   - CTx-protocols, CTx-charts (incl. supportive care)
   - SOPs and guidelines
   - patient's information and consent form
4. **Error management and error analysis**
   SAE and CTx ordering/application errors

Fig. 1. ECTU

II. CT - recruiting activities and promotion CCR / Med. I

Recruiting activities achieved through:

- Interdisciplinary tumorboards (attendance of ECTU-physicians in 11 boards)
- PSRB meetings for new + current CTs once per month
- 'Monday-OTM-Training' (weekly study training and education of Med. I team)
- 'Tuesday ECTU trainings' + education; 1x/month with Clinical Trials Center (CTC) UKF
- Daily clinic routine conference with attending physicians
- Cooperation with local medical centers (e.g.: iOMEDICO: ProTrials; flyer; broschure)
- Cross-linkage with CTx-management -> implementation of CT schedules in Blue Book
- Intranet: CT-overviews linked to study synopses
- "QuickQueck" (electronic pt-individualized study search)

Fig. 2. Study check Med 1 Intranet + QuickQueck

Promotions / public relations:

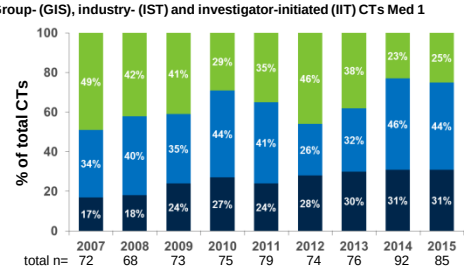
- ECTU flyer + broschure
- Homepage
- Feedback questionnaire ECTU-pts + regular feedback assessment
- Inspections and presentations (RP=Regional authority Baden-Württemberg, external guests & collaboration partners, DKH, DKG)

III. Clinical trials (CTs) 2007-2015: types (GIS, IST, IIT) & phase I - IV

Table 1. # of CTs 2015, enrolled pts and pt-# / CT in phase I-IV

	n_{total}	Phase I	Phase II	Phase III	Other
# of CTs	85	17	15	41	12
# of enrolled pts 2015 / total	249 / 811	22 / 63	17 / 88	82 / 225	128 / 435
Pt-# / CT 2015	2.9	1.3	1.1	2.0	10.7
Total pt-# / CT	9.5	3.7	5.9	5.5	36.3

Fig. 3. Group- (GIS), industry- (IST) and investigator-initiated (IIT) CTs Med 1



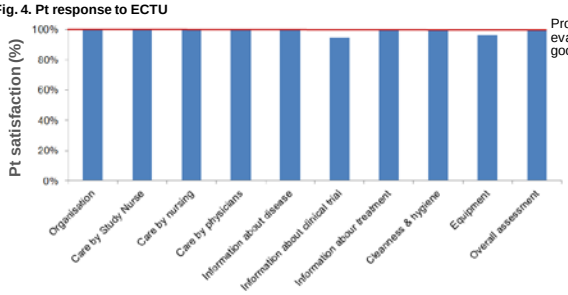
GIS = Study **G**roup **I**nitiated **S**tudy

IST = **I**ndustry **S**ponsored **T**rial

IIT = **I**nvestigator **I**nitiated **T**rial

IV. Pts' satifaction: analysis of feedback questionnaire (n=25) 2015

Fig. 4. Pt response to ECTU



Proporation of pts, that evaluate this issue as 'very good' or 'good'

V. Publishing and outcome reach activities

Fig. 5. Publishing activities

* * ** both 6th* and 2nd** editions scheduled 2016

Funding 2015/2016:

- Lohfert Preis: QM-CTx management
- DGHO best posters 2014+2015
- CCCF research funding
- Blue book educational grant funds

VI. ECTU: Early Clinical Trial Unit

To accomodate and facilitate phase I activities, the UKF/CCCF & Med. I established the ECTU that was a prerequisite for the CCCF/DKH approval in 2013. Clinical trial-CTx-application and pt care is performed through this unit 4 days/week, with all necessary equipment and medical logistic staff support being in place that form this highly efficient CCCF-unit.

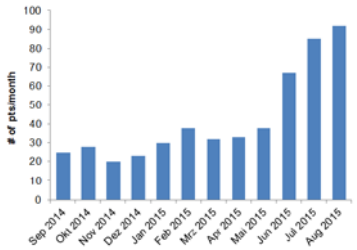


Fig. 6. ECTU patient contacts 2014-2015

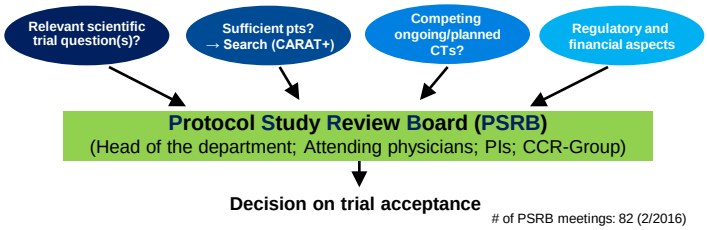
ECTU activities 2016:
Phase I CTs Med. I: 19, in preparation: 3
Med. II, Gyn, radio-oncology: use ECTU also for their phase I CTs

ECTU team:
GCP-approved physicians: 5
Study coordinators + Study Nurses: 4 + 10
Available doctors' assistants: 2 for CTs; being available: 5 days/week

Established collaborations
CCCF and all CCCF departments
Clinical Trials Center (Studienzentrum)
External partners: Quintiles, Oncotest, TCO partner with Novartis; Roche (in progress)

VII. Decision process for CT participation: protocol study review board (PSRB) meetings

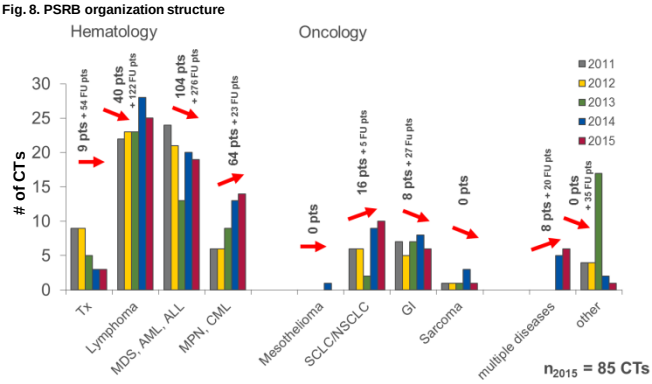
Fig. 7. PSRB organization structure



# of PSRB meetings: 82 (2/2016)

VIII. Pt recruitment 2011-2015 and # of CTs per disease entity

Fig. 8. PSRB organization structure



Conclusions

- 85 CTs recruited a total of n=811 pts and in 2015 n=249 pts
- Albeit pt inclusion into CTs becomes highly challenging, accounting for ~3 pts/CT in 2015, a total of ~10 pts/CT is achieved from study start to its end, which is excellent.
- CT diversity of phase I-III is well achieved in Med 1, with group- (GIS), industry- (IST) and investigator-initiated (IIT) trials of 25%, 44% and 31%, respectively.
- Increasing numbers of early CTs have been drawn to the newly established ECTU since 2013: initially 5 phase I CTs in 2013, greatly increasing to 17 in 2015 (19 + 3 in preparation 2016). Tumor entity-specific early CTs involve both solid tumor and hematologic malignancies as shown from the ECTU start in 2013 through 2016.
- Pt response on this ECTU has been exceptionally good: organization, study nurses, medical support, information provision and other aspects were judged as excellently performed and the unit premises and hygiene are highly appraised.
- The increase in phase I early CTs has been accompanied with an increase in pt enrollment and impressive pt numbers being treated per month within this unit.
- CT-participation at our center is eagerly and democratically discussed and decided upon in monthly CCR-scheduled and -organized PSRB-meetings; 82 being performed since its establishment.
- The CCR-group enthusiastically supports CT-recruitment strategies (e.g. tumorboards, PSRB, educational programs, ProTrials, cross-linkage to CTx-management, intra-/internet, QuickQueck).
- The ECTU supports the UKF expertise in clinical research that is of utmost importance for new drug development; the new ITZ building will lay the ground for additional advances.
- Our CCR-team offers valuable support in CT-preparation and -conduct, CARAT+ data acquisition/outcomes research, QM-initiatives and error management support. Audits by the local and external authorities proved that quality standards are fully achieved.
- Publishing activities of our department add to our expertise.

References

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