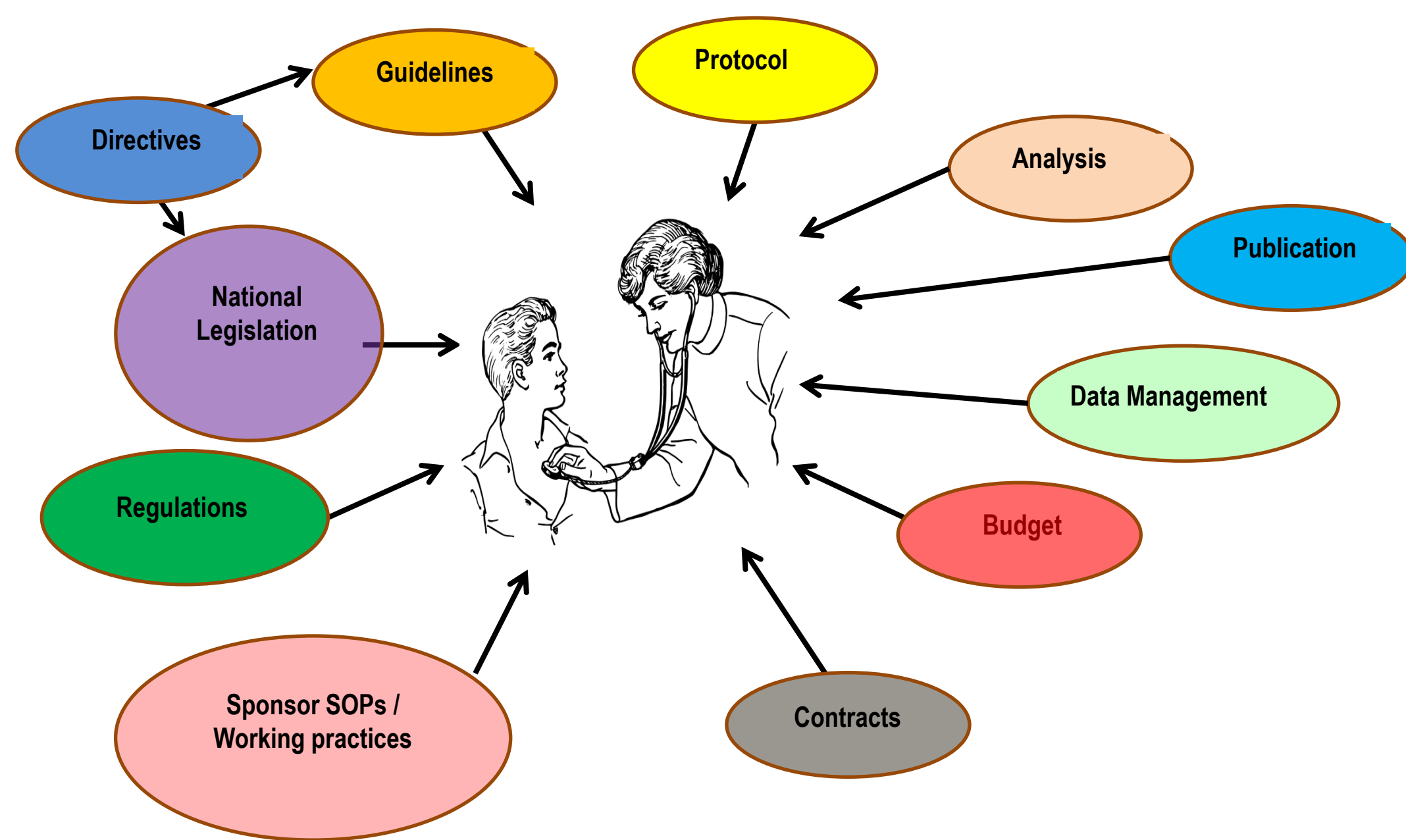


What's Involved in a Clinical Trial?



Clinical Trials at the EBMT

The EBMT has a Clinical Trials Office (CTO), which is based in London and Leiden. The CTO offers the following services for EBMT sponsored trials:

- Protocol design and feasibility
- Competent Authority and Ethics Committee submissions
- IMP management
- Pharmacovigilance, including IDMC
- Recruitment and retention services
- Monitoring and centre/vendor oversight
- Contract negotiation and budget management
- Quality management and auditing
- Data management and statistics
- Report writing

The CTO runs the following types of prospective clinical trials

- Phase II-IV, including post-authorisation safety studies
- Investigator initiated trials

The CTO had a routine MHRA (UK competent authority) GCP inspection in May 2013. The CTO is preparing for the implementation of the CT Regulation.

The CTO will be presenting to Data Managers on Monday 23rd March 2015 – 14.00 – 14.40 (Room 3B/01):

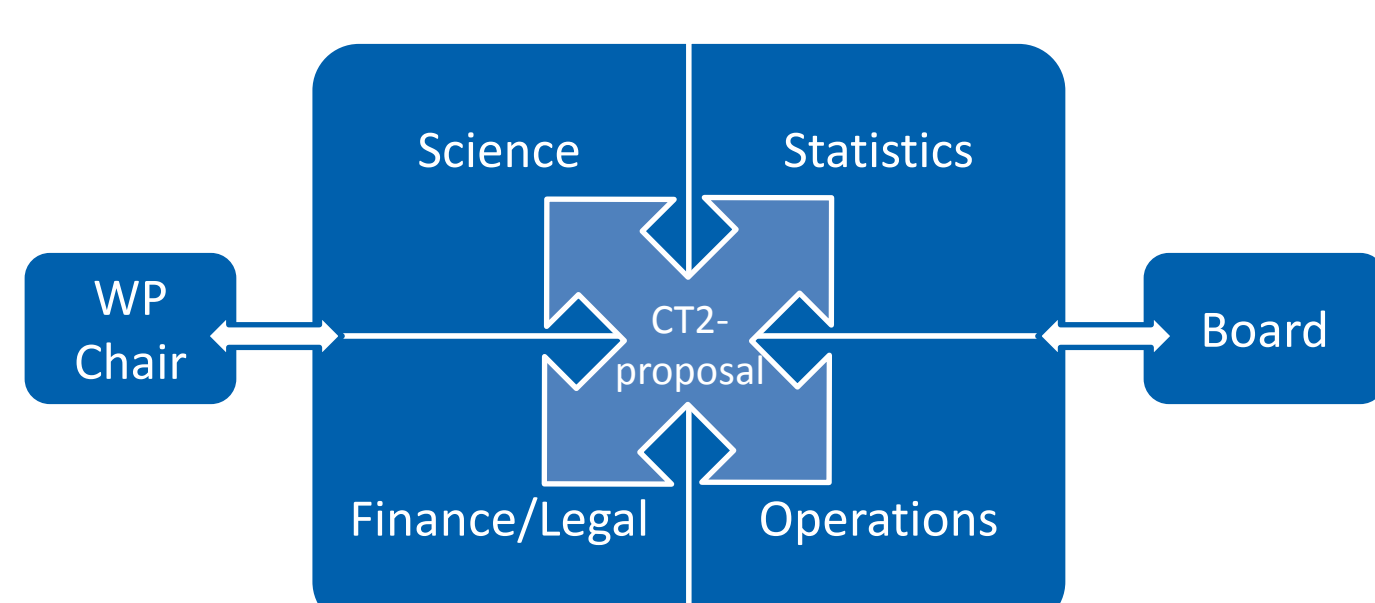
Clinical trials – what is necessary to provide good clinical data for clinical trials?

How to start a trial at the EBMT – the CT2 committee

Since 2011, all trials sponsored by the EBMT have been reviewed and selected for sponsorship by the EBMT CT2 committee, which is chaired by Charlie Craddock.

The CT2 committee is now open for proposals until 17 April 2015.

The CT2 committee includes 5 physicians who review the science and EBMT staff who review the statistics, finance/legal and operations of each proposal.



Further details are available here: <http://www.ebmt.org/Contents/About-EBMT/Who-We-Are/Committees/Pages/CT2-EBMT-Committee%E2%80%93guidance-for-Investigators.aspx>

Clinical Trials open to recruitment

Trial	Coordinating Investigator	Status
Elderly AML*	Dietger Niederwieser	Recruiting
RACE [‡] Aplastic Anaemia	Regis Peffault de la Tour / Antonio Risitano	Submitted to CAs and ECs
Letermovir PN001 [^] CMV prophylaxis	Merck	Recruiting

* Investigator meeting:

[‡] kick-off meeting: 15 April 2015, St. Louis Hospital in Paris, France

[^] Recruitment workshop: Monday 23 March 2015 6-7pm, Room: 3B/12 (B3 level)

Clinical Trials (closed to recruitment – analysis phase)






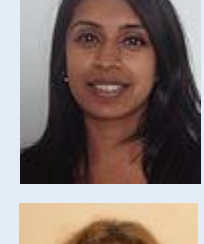
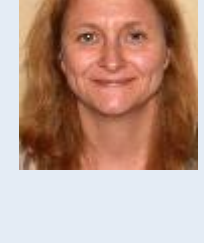
Trial	Coordinating Investigator	Publication status
RICMAC*	Nicolaus Kröger	Analysis phase
ASTIC	Chris Hawkey	Submitted for publication
LYM1	Ruth Pettengell	Long term follow up

* Presented at the presidential symposium: Monday 23 March 12.05, Harbiye Auditorium

Publications in 2014 and 2015

- Van Laar JM, Farge D et al. JAMA. 2014 Jun 25;311(24):2490-8:
ASTIS: Autologous hematopoietic stem cell transplantation vs intravenous pulse cyclophosphamide in diffuse cutaneous systemic sclerosis: a randomized clinical trial.
- Mancardi GM, Saccardi R et al. Neurology. 2015 Feb 11; Epub ahead of print:
ASTIMS: Autologous hematopoietic stem cell transplantation in multiple sclerosis: A phase II trial.

The CTO Team

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Please contact Liz Clark or Alain Barrois for any CT questions.