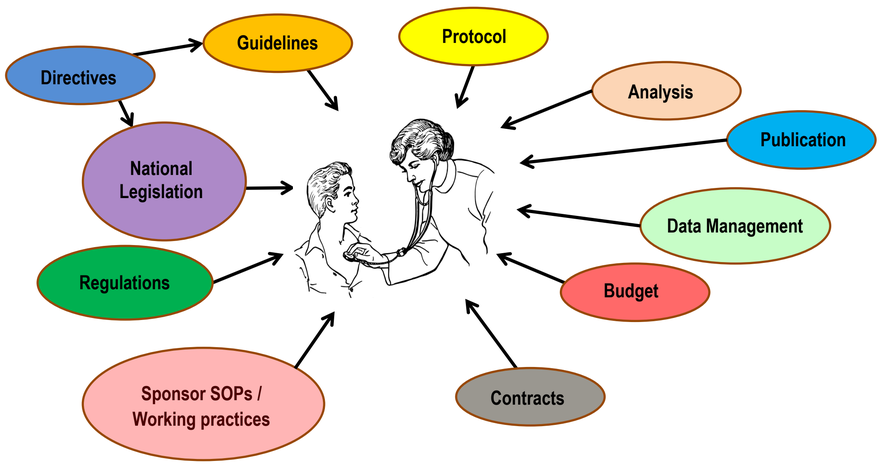
EBMT Clinical Trials Office

Information (Leiden and London) & Update MK-8228 CMV 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

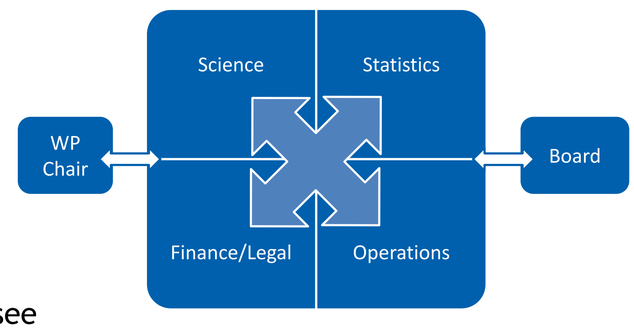
The CTO runs the following types of prospective clinical trials:

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

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 committee includes at least 4 physicians who review the scientific content and EBMT staff who review the statistics, finance/legal and operations of each proposal. For further details, see the *Guidance For Investigators* on the EBMT website /Committees.



Publications in 2015

ASTIMS **Mancardi GL, et al.** *Neurology*, 2015 Mar 10; 84(10):981-988. Autologous Hematopoietic Stem Cell Transplantation in Multiple Sclerosis: A Phase II Trial.

ASTIC **Hawkey CJ, et al.** *JAMA*, 2015; 314(23):2524-2534. Autologous Haemopoietic Stem Cell Transplantation for Refractory Crohn Disease: A Randomised Clinical Trial.

The CTO team

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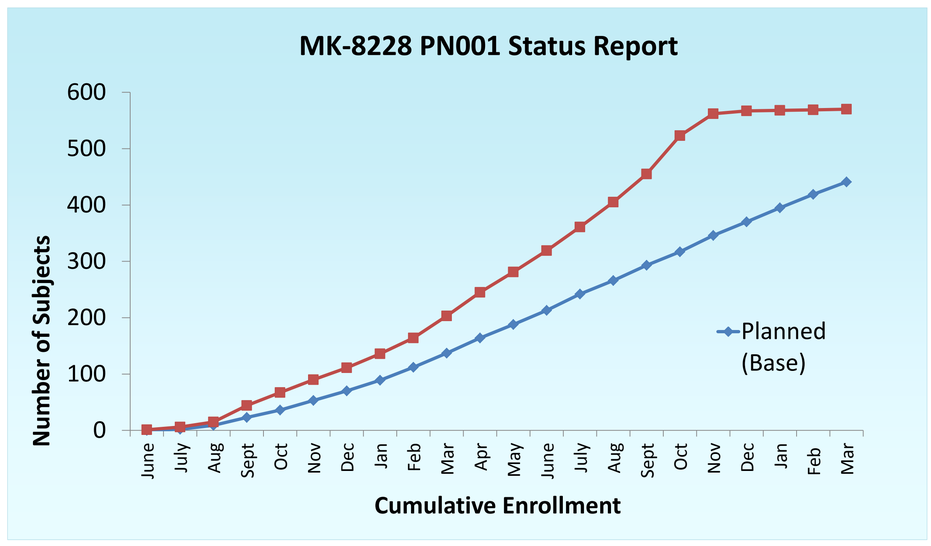
MK-8228 CMV Trial

Trial to Evaluate Safety and Efficacy of MK-8228 (Letermovir) for the Prevention of Human Cytomegalovirus (CMV) Viremia and/or Disease in Adult CMV Seropositive Allogeneic HSCT subjects

A Merck (MSD) sponsored trial (73 sites, 20 countries), with EBMT supporting 50 of the sites (17 countries) by providing a recruitment and retention service.

Design A phase 3, multi-centre placebo-controlled trial of approximately 540 patients with a 2:1 randomisation. Recruitment started in June 2014 and ended in March 2016 (recruitment was achieved ahead of time).

Enrollment



EBMT Role

- Monitoring recruitment and retention in EBMT supported sites, identifying struggling sites and providing PI led TC support to those sites.
- Holding annual workshops for PI's attending the EBMT Annual Conference.
- Arranging PI led group TC's for PI's and other site staff.
- Having regular TC's with Merck HQ to discuss any issues and mitigation measures.

Participating countries and patients

Region	Country	Number of sites opened per country	Total patients randomised to March 2016
Europe	Austria	2	28
	Belgium	2	32
	Finland	1	14
	France	3	21
	Germany	4	34
	Italy	4	32
	Lithuania	1	5
	Poland	2	12
	Romania	2	7
	Spain	5	32
	Sweden	2	20
	UK	3	12
EEMEA	Turkey	6	36
Asia/Pacific	New Zealand	2	9
	Japan	5	36
	South Korea	5	9
North America	Canada	1	19
	US	21	203
Latin America	Brazil	1	1
	Peru	1	8
Total (EBMT supported)	17 countries	50	358
Total (non-EBMT supported)	3 countries	23	212
Total (all)	**20 Countries**	**73**	**570**

Important issues

- Week 24 visit is a vital endpoint and ***must*** be completed. Sites should use the treatment calendar to determine the date. Sites will also receive a reminder about the patients concerned. Data should be entered into EDC within 5 days.
- Record prescription of Campath or ATG in the eCRF under prior meds or concomitant meds.
- Inform Merck / MSD as soon as CMV disease is ***suspected***. The essential documents can then be collected and assessed. CMV does not need to be confirmed prior to notification.
- Sites must ensure that the protocol is followed and data is completed in time. This will lower the number of protocol deviations.

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