







Dear all,

Executive Committee (ExCom)

The PM ExCom held its 6th meeting October 14. Assistant Professor Sisse Ostrowski was welcomed as representative from the diagnostic departments. Sisse Ostrowski works in Department of Clinical Immunology, blood bank division. Sisse Ostrowski is also leading the Immunological Characterization SIG working on a proposal for a revised characterization panel.

ExCom approved the project "Transfusion transmitted Hepatitis E Virus in multiply transfused immune deficient patients" submitted by Harritshøj, Ullum et al. (link) from Dept Immunology.

ExCom noted, that recruitment to the prospective cohort still is below the benchmark, but improving. A first version of the statistics displaying the rate of recruitment in the individual departments, and in the patient groups agreed upon, was demonstrated, and will soon be available on the web.

Scientific Interest Groups (SIGs)

Each of the SIGs have their own web-page under PERSIMUNE (www.persimune.org) where you can read about the scope, the leadership, publications of interest and next meetings of all the SIDs. Also a link for interested scientists to join the mailing list from the specific SIG is available. Likewise a PERSIMUNE calendar is now available from which you can directly export meetings to your Outlook calendar.

The 2015 European AIDS Clinical Society (EACS)

Award to Jens Lundgren Jens Lundgren received the EACS award for excellence in HIV Medicine and the recognition for major contributions to the European AIDS Clinical Society. Prof Nathan Clumeck, Chair of the EACS Awards Committee, announced the winner at the opening ceremony of the 15th European AIDS Clinical Conference in Barcelona on 21 October 2015. See also summary by Rigshospitalet





Important contract won by PM and Dept of Genomic Medicine

The first results of the START study was recently published in N Engl J Med. One of several pending questions from that study is the impact from transmitted drug resistant HIV in locations without access to routine resistance testing. A total of 54% of the 4685 participants came from low to moderate income countries without access to routine resistance testing. Without access to this test, the clinician is unable to tailor antiviral therapy. In competitions with laboratories in the USA, Center for Genomic Medicine at Rigshospitalet was chosen as sole global laboratory to generate data on viral characteristics from the participants in START. The data will be used to generate prevalence information on transmitted drug resistant virus, and the extent that lack of real-time access to this test affect the ability of antiviral therapy to fully and durably suppress viral replication. Dr Rasmus Marvig is the PI for this activity, which is funded by a specific grant from NIH, USA – congratulations to Rasmus for this major achievement.

Scientific Advisory Committee (SAC) - Review Procedures

The HEV project mentioned above was the first PM project, that – approximately – followed the intended review and approval process. The Scientific Advisory Committee met by transatlantic and trans-North See telephone links, and agreed on a proposal for the future <u>PERSIMUNE proposal review procedure - Scientific Advisory Committee</u>, which was subsequently approved by the ExCom.

The SOP operates with ad hoc chairpersons in a process designed for speed and consensus, so that the ExCom will be able to decide on projects on the basis of a review summary.

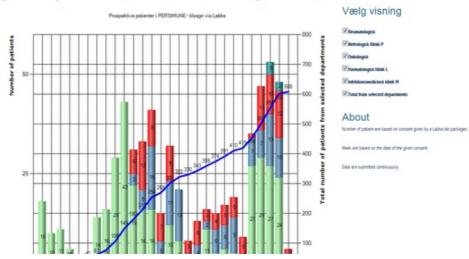
The Neutropenia Scientific Interest Group wins award from the Danish Cancer Society

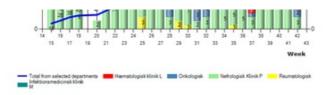
The SIG submitted a research project to the 'Knæk cancer' call for proposals. The <u>project</u> was evaluated positively and picked out for funding for a PhD position, depending on the amount of charity donations the Danish Cancer Society will be able to raise during the Knæk Canver campaign.

Prospective Cohort

An interactive graph where departments can choose to see enrolment in their own department or departments of their choice – break-down by patient group will be available shortly when data capture from the RegionH server are complete and stable. Please see the real-time graph at: http://chipadm/persimune-in-figures/enrolment (copy link to your browser - only works inside RH firewall).

Prospektive patienter i PERSIMUNE – tilsagn via Labka





The establishment of "the brown biobank" began in June. However, based on the first experiences the setup has now been slightly revised. After a quick study of the literature, the biobank group decided that collection at home by the patient and subsequent shipment to biobank via mail was the practical solution. Feces sampling and mailing is already used in the Danish colorectal cancer screening, and the collection kits and procedure has been validated according to the microbiome literature. As part of the microbiome specimen collection, also sputum specimens will be collected. In the first phase, these biobank specimens will be collected from oncology and hematology patients likely to develop neutropenia.

Retrospective Cohort

Region Nordjylland has taken over the responsibility for administration of lab portal MedCom and PERSIMUNE has renewed the data transfer agreement to comply with the new set-up.

The data warehouse now captures data on 37.000+ historical patients on all national lab parameters, on medication from EPM and vital parameters from KISO and on diagnosis and dates of contact/ causes history from RegionH server – the dataset we can access for the latter is not fully complete, but the Region is working on ensuring completeness and stability.

The question of access to data is a hot topic these days, and the authorities involved in granting access are jittery, whether they be regional or national authorities. It has been reassuring to observe that the obvious beneficial intentions behind the PM projects have cleared the way for access, even in the face of legal and/or bureaucratic concerns.

Making data legible - "mapping"

The enormous work on standardizing the data captured is ongoing – all lab analysis elements have been through a first round of review categorizing clinical chemical and microbiology analysis as: 0) not relevant; 1)

To be standardized by clinical specialists; 3) Package analysis; 3) Analysis using other material than blood (second priority), 4) Other second priority

Next steps will be to have all clinical specialists on board in reviewing and standardizing analysis, for more detail see document <u>here</u>

Three new PhD students in PM

The PhD posting in September resulted in an extremely qualified field of applicants, actually so attractive, that it was decided to secure the three most qualified, all MDs with a few years of clinical experience. They are

Theis Aagaard

Department of Pulmonary and Infectious Diseases,

Nordsjællands Hospital.

Boje Kvorning Ehmsen

Coordinating MD at the Emergency Medicine department,

Køge Hospital CUH

Danish Defence Health Service

Michael Moesmann Madsen

Internal Medicine PGY-1, KBU-læge

Silkeborg Hospital

They will begin work simultaneously on November 1st, and will formulate their respective PhD application during the first few months. All the projects will of course depend heavily on data access and data quality, and the expectation is, that the trio will be a very active part in the data mapping process, primarily in the enormous amount of data in the retrospective cohorts.

PM publications

- 1. Development and Validation of a Risk Score for Chronic Kidney Disease in HIV Infection Using Prospective Cohort Data from the D:A:D Study, A Mocroft, JD Lundgren, M Ross, M Law, P Reiss, O Kirk, C Smith, D Wentworth, J Neuhaus, C A. Fux, O Moranne, P Morlat, MA Johnson, L Ryom, D:A:D study group, the Royal Free Hospital Clinic Cohort, and the INSIGHT, SMART, and ESPRIT study groups PLoS Med 2015 March 31, 12 (3)
- 2. Clinical Application of Variation in Replication Kinetics During Episodes of Post-transplant Cytomegalovirus Infections, IP Lodding, H Sengeløv, C da Cunha-Bang, M Iversen, A Rasmussen, F Gustafsson, JG Downing, J Grarup, N Kirkeby, CM Frederiksen, A Mocroft, SS Sørensen, JD Lundgren, On behalf of the MATCh Programme Study Group EBioMedicine; 2015 Vol 2, Issue 7 p.669-705
- **3. Factors Associated with Plasma IL-6 Levels During HIV Infection**, ÁH Borges, JL O'Connor, AN Phillips, FF Rönsholt, S Pett, MJ Vjecha, MA French, JD Lundgren, INSIGHT, SMART and ESPRIT Study Groups and the SILCAAT Scientific Committee

 J Infect Dis. 2015 Feb 26. pii:jiv123
- **4. Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection, The INSIGHT START Study Group**, JD Lundgren, AG Babiker, F Gordin, S Emery, B Grund, S Sharma, A Avihingsanon, DA Cooper, G Fätkenheuer, JM Llibre, J Molina, P Munderi, M Schechter, R Wood, KL Klingman, S Collins, HC Lane, AN Phillips, JD Neaton, The INSIGHT START Study Group
 The New England Journal of Medicine 2015 July 20th, DOI:10.1056/NEJMoa1506816

This Newsletter

This Newsletter will be circulated broadly at RH and to the wider PM group and posted on www.PERSIMUNE.org, likewise announced on PM social media platforms

Thanks, Jens Lundgren



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