Biennial report

Study Groups

Title of the study group: EULAR European Consensus Finding Study Group on Laboratory Investigation in Rheumatology (ECFSG)

Study Group Leader's name: Johan Rönnelid
Date of annual report submission: February 26, 2020

Summary of last year's activities:
The aim of the ECFSG is to achieve consensus in how laboratory results in the field of autoantibody diagnostics are evaluated: a laboratory result should be the same, wherever the result is obtained. This is achieved by arranging an interactive consensus exercise and discussion forum. After having evaluated tentative samples the ECFSG steering board meet every year in the fall to decide on the agenda and 10 suitable samples, to be distributed to European laboratories in the beginning of December every year. The samples are tested blindly for a variety of autoantibodies, Results are collected and analysed centrally by steering board members. The final evaluation is presented and discussed at a study group meeting open to all participants in conjunction with the European Workshop for Rheumatology Research (EWRR) every year. Results are discussed in the context of the patients' clinical pictures and the use of specific assays, including performance of specific company-produced assay kits. For that reason, attendance to the study group meetings are restricted to scientific participants, excluding representatives from assay manufacturers.
Thirtyeight European laboratories involved in serological diagnosis of rheumatic diseases participated in the serum round 2018/2019 and 36 labs in 2019/2020, respectively. We use to invite an external speaker to our open meetings, in 2019 it was Dr Bernard Fox who lectured about the preparation of the new international WHO standard for anti-dsDNA antibodies. (There was no invited speaker at the 2020 meeting as many board members had other conflicting engagements.)

The study group has worked in this way since it was founded in 1988, and the participation is highly evaluated by many participants as an evaluation of quality of their analyses, and many regularly request certificates of participation and attendance.

Since 2014, the ECFSG has adopted the complementary agenda to participate in the international evaluation of new reference reagents for autoantibodies. Sera/plasma samples which are tentative new reference reagents with the following specificities have been evaluated:
2013/2014: anti-dsDNA (now publicly available as the 2nd WHO standard, NIBSC 15/174)
2014/2015: ACPA
2015/2016: anti-PR3 (now available from the EU Science Hub, denoted ERM-DA483/IFCC)
2015/2016: anti-MPO (now available from the EU Science Hub, denoted ERM-DA476/IFCC)
2015/2016: IgG anti-β2GP1
2016/2017: anti-GBM
2017/2018: anti-DFS70 (dense fine speckled ANA, 70 kD)
2019/2020 RF/ACPA (the upcoming new WHO standard, planned to be released late 2020 at the earliest)

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This new approach has definitely increased the general visibility of our work, and ECFSG is now widely regarded as one of the organisations working in autoantibody standardisation at the international level. Johan Rönnelid and Martin Blüthner have represented ECFSG on the International Consensus on ANA Patterns (ICAP) meeting and the International Autoantibody Standardization (IAS) meetings, both in Dresden in September 2019, and Johan Rönnelid is invited to lecture on the WHO anti-dsDNA reference standard on the 12th International Congress on Autoimmunity in Athens, May 2020. More labs than we can accommodate want to join our activities, and we demand a high degree of participation from laboratories each year, to remain as participant the following year.

The direct communications with EULAR have been more intensive during the last years, and the study group is now represented on each annual European EULAR congress. We have a five-year EULAR project funding covering costs for meetings and transportation of samples until 2021. This money is used according to the budget provided to EULAR, for our board meetings two times/year, sample transports and representation at up to one meeting/year. We are currently discussing to also reimburse costs incurred by patients when donating blood for our studies; this has been requested by a lab manager from Poland. (Participating laboratories provide sera based on local ethical clearances and with informed consent.)

ECFSG steering committee 2020:
Dr Johan Rönnelid, University Hospital, Uppsala, Sweden (chairman)
Dr Charlotte Dahle, University Hospital, Linköping, Sweden (secretary)
Dr Dörte Hamann, University Medical Center Utrecht, the Netherlands (treasurer)
Dr Martin Blüthner, MVZ Labor PD Dr. Volkmann und Kollegen GbR, Karlsruhe, Germany
Dr Thomas Rose Charité University Hospital, Berlin, Germany (since 2019)

ECFSG publications since last biennal report in 2018:

1. Andrade LEC, Klotz W, Herold M, Conrad K, **Rönnelid J**, Fritzler MJ, von Mühlen CA, Satoh M, Damoiseaux J, Cruvinel WM, Chan EKL; Executive Committee of ICAP. International consensus on antinuclear antibody patterns: definition of the AC-29 pattern associated with antibodies to DNA topoisomerase I. Clin Chem Lab Med. 2018 Sep 25;56(10):1783-8.
2. Dellavance A, Baldo DC, Zheng B, Mora RA, Fritzler MA, Hiepe F, **Rönnelid J**, Satoh M, Garcia De La Torre I, Wener MH, Chan EKL, Andrade LEC. Establishment of an international autoantibody reference standard for human anti-DFS70 antibodies: proof-of-concept study for a novel megapool strategy by pooling individual specific sera. Clin Chem Lab Med 2019;57(11):1754-63
3. Fox B, Hockley J, Rigsby P, Dolman C, Meroni PL, **Rönnelid J**. A WHO Reference Reagent for lupus (anti-dsDNA) antibodies: international collaborative study to evaluate a candidate preparation. Anna Rheum Dis 2019 Dec;78(12):1677-80.

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