

Linking a cytokine/protein biomarker signature with clinical outcome may help to identify and classify patient cohorts. Thus "intelligent" cytokine signatures can be used as biomarkers in human inflammatory diseases. There are however various risks associated with this approach; often it is impossible to obtain material from the site of inflammation and there are various often not well-known technical aspects crucial to obtain reliable and usable results. Although standardization has been prominent in day to day clinical practice, standardization of sample collection and laboratory assessments remains suboptimal. Inconsistency in sample collection can affect the results of biological assays and thus several characteristics require thorough evaluation and standardization. This standardization is not limited to assay validity and reproducibility but also pre-analytical treatment and appropriate specimen types.

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SP0068 CLINICAL INSIGHTS INTO JIA HETEROGENEITY

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Several epidemiologic surveys have documented a remarkable, yet unexplained, disparity in the prevalence of juvenile idiopathic arthritis (JIA) subtypes among different geographic areas or ethnic groups. Moreover, the therapeutic approach to JIA is not standardized and the availability of the novel and costly biologic medications is not uniform throughout the world. This disparity may have significant impact on disease outcome. The multinational study of the Epidemiology, treatment and Outcome of Childhood Arthritis (EPOCA study) is aimed to obtain information on the variability of JIA phenotypes in different geographic areas, the therapeutic approaches of pediatric rheumatologists practicing in diverse countries, and the disease status and outcome of children with JIA currently followed worldwide. Participation in the study was proposed to all pediatric rheumatology centers that are part of the Pediatric Rheumatology International Trials Organization (PRINTO), and to several centers in the US and Canada. Each center was asked to enroll 100 consecutive JIA patients or all consecutive patients seen within 6 months. Each patient received a retrospective and cross-sectional assessment. Parent- and child-reported outcomes were recorded through the administration of the Juvenile Arthritis Multidimensional Assessment Report (JAMAR). Participating countries were grouped into 6 geographic areas. Patients were then grouped according to their country's gross domestic product per capita (GDP) and the total expenditure on health per capita (HE) (source www.who.org). Currently, 8,325 patients from 44 countries have been entered in the web database. Comparison of main epidemiology, treatment, and outcome features across the different geographic areas was performed. Patients living in countries with GDP or HE below the median had lower frequency of remission, higher median cJADAS, higher frequency of damage, and were less frequently prescribed biologic DMARDs. These results were confirmed when analyses were conducted only in oligoarthritis or polyarthritis patients. These results provide further evidence of the wide difference of JIA characteristics across geographic areas in terms of age at disease onset, subtype prevalence, and frequency of anterior uveitis. Overall, patients living in non-Western countries had higher levels of disease activity and cumulative damage than patients followed in North America and Western Europe. This disparity in disease outcomes may be partially due to differences in the availability or affordability of biologics, as confirmed by the evidence of worst outcomes in countries with lower GDP or HE.

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EULAR - EMA session

SP0069 REGISTRIES IN MUSCULOSKELETAL DISEASES AND THEIR REGULATORY USE

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Patient registries collect information about individuals sharing health-related characteristics, for example, a particular disorder, a treatment or a procedure. While randomised controlled trials typically provide the primary evidence supporting marketing authorisations for new medicines, the patients studied may not be fully representative of everyone ultimately receiving the medicine and the trials may provide limited information about the natural history of the disorder. Information collected in patient registries is potentially of value for filling these evidence gaps in certain situations and for providing post-marketing safety and effectiveness information. Multiple stakeholders stand to benefit from using registry information in this way including patients, healthcare providers, policy makers, manufacturers and healthcare regulators.

In 2014, the EMA commenced a Registry Initiative aiming to optimise the use of registries in supporting medicines authorisations. Establishing a strategy of early engagement between marketing authorisation applicants and registry holders and a task force to support activities, a pilot phase was undertaken aiming to understand the barriers and enablers in using registries to support marketing

authorisation applications and to inform the development of recommendations to optimise their use.

On 28 October 2016 the Agency organised Patient Registries Workshop to collect and discuss the information about experience from different patient registries in various therapeutic areas. The topics included:

- Benefits of registries for regulators
- Benefits of registries for HTA and payers
- Benefits for industry
- Benefits for clinicians and researchers
- Benefits for patients
- Challenges in collaboration between registries
- Technical challenges
- Governance
- Sustainability

Conclusions of the pilot and the workshop have been utilised in the following activities including workshops to support registries in individual diseases.

There are multiple advanced registries in RA and JIA. Utilisation of outcomes of these and other existing or newly planned registries in other musculoskeletal diseases for regulatory purposes current environment offers new opportunities that require further analyses and collaboration.

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SP0070 NEWS FROM OMERACT – IMAGING AND MORE

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Objective In rheumatoid arthritis (RA), MRI provides earlier detection of structural damage than radiography (X-ray) and more sensitive detection of intra-articular inflammation than clinical examination. This analysis was designed to evaluate the ability of early MRI findings to predict subsequent structural damage by X-ray. **Methods** Pooled data from four randomised controlled trials (RCTs) involving 1022 RA hands and wrists in early and established RA were analysed. X-rays were scored using van der Heijde-modified or Genant-modified Sharp methods. MRIs were scored using Outcome Measures in Rheumatology (OMERACT) RA MRI Score (RAMRIS). Data were analysed at the patient level using multivariable logistic regression and receiver operating characteristic curve analyses.

Results Progression of MRI erosion scores at Weeks 12 and 24 predicted progression of X-ray erosions at Weeks 24 and 52, with areas under the curve (AUCs) of 0.64 and 0.74, respectively. 12-week and 24-week changes in MRI osteitis scores were similarly predictive of 24-week and 52-week X-ray erosion progressions; pooled AUCs were 0.78 and 0.77, respectively. MRI changes in synovitis at Weeks 12 and 24 also predicted progression of X-ray joint damage (erosion and joint-spacenarrowing) at Weeks 24 and 52 (AUCs=0.72 and 0.65, respectively).

Conclusions Early changes in joint damage and inflammation detected with MRI predict changes in joint damage evident on subsequent X-rays. These findings support the use of MRI as a valid method for monitoring structural damage in short-duration RCTs.

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Barrier free employment for young people with RMDs

SP0071 YOUNG PATIENTS: READY, BRILLIANT AND ABLE TO WORK!

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In May 2016, European Young Patients Group, an initiative representing young patients from the European Patients' Forum (EPF) and the European Multiple Sclerosis Platform (EMSP), organised a workshop in the framework of the European Youth Event (EYE) 2016 in Strasbourg that corresponded with one of the five main programme themes titled, Exclusion or Access: Crackdown on Youth Unemployment.

The physical and emotional symptoms of chronic conditions, together with social stigma and attitude, create significant barriers to young patients in the job market. With appropriate support, they, like all enthusiastic young people, can be assets for employers. Through interactive discussion, creative expression, education and open dialogue, the workshop aimed to challenge expectations and inaccurate perceptions about the abilities of young people with chronic conditions, tackle societal beliefs and stereotypes of individuals with chronic conditions, stimulate discussion to explore concrete solutions and develop practical actions for young people and their allies accessing employment and steer change to ensure young patients benefit from equal opportunities and treatment at work. By addressing these specific objectives, the workshop was to ultimately raise awareness of the extra burdens faced by young people with chronic conditions transitioning from education to employment, as well as bringing public attention to the stigma and discrimination that exists at both the recruitment stage and in relation to employees disclosing their health conditions. It also was to compliment and