subtypes of JIA. In for example systemic JIA, we have learned that the systemic inflammatory mechanisms at onset of this disease, are primarily driven by innate immune cells and their inflammatory cascades. Both IL-1 and IL-6 blockade in sJIA have resulted in high response rates of sJIA patients.

Additional progress still has to be made in efficacy, cost reduction, minimization of side effects and taper and stop strategies of maintenance drugs. To ensure that the right goals are set, patients (and/or their parents in paediatric disease) should be involved in important research questions and goals. In addition, if we really aim to take the next step in improving the outcome and life of our patients, clinical innovations need to go hand in hand with basic discoveries to really affect care for patients.

Current clinical trials rely on the recognition of clinical phenotypes and have strict inclusion criteria. In these trials with more or less homogenous patient cohorts, response rates to a specific treatment are evaluated and compared to placebo or current standard therapeutics. This has resulted in the registration of multiple biologic therapies for various JIA subtypes and to significantly improved response rates and disease outcomes for most JIA patients. However, still a major question in clinical practice remains: which biological to start in which patient and when.

Agreement on several consensus treatment plans in clinical practice for different subtypes of JIA, will help in comparing responses to registered therapeutics. However, to book further progress in the care for JIA patients, what we really need is a more molecular based set of classification criteria, or disease taxonomy, of JIA subtypes and (sets of) biomarkers for disease course/therapy response and biomarkers to assess subclinical disease activity. These criteria and biomarkers will enable informed decisions on the start as well as tapering/stop of maintenance therapy. Such a classification, as well as the discovery and validation of novel/promising biomarkers are likely to be developed in collaborative cohort studies with new onset JIA patients that are prospectively followed and sampled over time.

Facilitating the translation from bench to bedside is crucial for addressing the major current challenges in JIA management. When successful, it will set new standards for safe, targeted and personalised medicine in JIA.

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SP0020 HOW DIGITAL TOOLS CAN HELP TO CROSS BORDERS IN INTERNATIONAL COLLABORATIONS

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When people think of digital health, they generally think of health and wellness mobile apps, or wearable sensor devices like Fit Bit or the Apple Watch. But digital technologies are much more than that. Today's advanced digital health has evolved into software platforms that can connect and support patients, their families and connect them to their health systems, enabling outcomes research and management with direct input from networks of patients that can connect across geographical divides. And these systems enable communication between medical systems, enabling hubs and spokes of networked researchers and their patients that promote data capture, information sharing and enhanced communications to patients- by meeting them where they are. These new models are driving the ability to study interventions in real world contexts including patients' between visit activities and their engagement with multiple layers of the healthcare teams thereby promoting integrated research and care. With all of these capabilities, the question remains, "will the medical research community be ready to embrace it?"

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WEDNESDAY, 13 JUNE 2018

Ultrasound basic I

SP0021 HOW TO ASSESS DACTYLITIS+DEMO

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Dactylitis is a hallmark feature of psoriatic arthritis (PsA) and other spondyloarthritis, although it can also be present in other conditions such as sarcoidosis, gout or infections. Regarding PsA, dactylitis, which occurs in 30% to 50% of patients, is a highly discriminative feature for PsA diagnosis in early disease as well as a predictor factor for structural damage development. On ultrasound, dactylitis is a complex and heterogeneous "imaging syndrome" that includes a variety of elementary lesions, i.e. enthesitis (finger extensor tendon, collateral ligaments, flexor fibrous

sheaths, flexor pulleys, functional entheses), tenosynovitis, paratenonitis, synovitis, subcutaneous/peritendon tissue inflammation, and proliferative and erosive bone changes. High resolution B-mode ultrasound offers a detailed anatomical imaging of the different lesions present in dactylitis as well as Doppler ultrasound provides information on the inflammatory activity of the involved structures and tissues.

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SP0022 HOW TO ASSESS BONE EROSIONS – INDICATIONS, PITFALLS AND NEW TECHNIQUES + DEMO

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Detection of bone erosions is essential for the early diagnosis, the prediction of future bone damage, and the monitoring of therapeutic outcomes in patients with rheumatoid arthritis (RA).

Yet, bone erosions are not pathognomonic for RA. They occur in many other disease entities. Presence of bone erosions is characteristic for mixed connective tissue disease, juvenile idiopathic arthritis, gout, hemochromatosis, pigmented villonodular synovitis, among others. It is not uncommon in osteoarthritis. Bone erosions can be detected at entheses in spondyloarthropathy and in the joints of patients with psoriatic arthritis. Erosive changes can also be seen in bone neoplastic disease.

Conventional radiography is still considered the basic imaging method of detection of bone erosions, as well as a monitoring tool. However, more modern imaging techniques are becoming more widely used. They include ultrasonography, magnetic resonance imaging and computed tomography. Apart from higher sensitivity for detection of bone erosions, the new techniques offer simultaneous visualisation of soft tissues. Their role in follow-up of patients with erosive disease as well as erosive progression is still a subject of research.

In the short time allowed, the presentation will also address localization, pitfalls and characteristic appearance of bone erosions in main rheumatological diseases.

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SP0023 HOW TO ASSESS MECHANICAL AND INFLAMMATORY TENDINITIS + DEMO

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Tendinopathy is a frequent disorder that may last for several years and impair the quality of life of athletes, non-athletes and patients with inflammatory joint diseases where tendinopathy is a frequent complication.

The diagnosis can often be made alone by clinical examination, but in the selected cases, imaging can be determined for the correct diagnosis and treatment.

US has several significant advantages over MRI. The greatest strength of the US is that it is interactive and the examiner is in contact with the patient, and any site of reported pain or tenderness can be directly correlated with its real-time scan appearance on the screen. The ultrasonographer can make use of the dynamic real-time character of US, so that tendons can be studied throughout their range of motion and side-to-side comparison is always available during the US examination. This unique advantage over other cross-sectional imaging modalities like MRI is of course especially applicable in the evaluation of mobile structures such as tendons. Tissue with few mobile protons emits little or no signal and, therefore, the internal architecture of the tendon is not well demonstrated in MRI. In contrast, US shows the fine internal structure of tendons, and US therefore pictures the anatomic border of the tendon more precisely than MRI, and in agreement with this the "standard deviation" (SD) and "range of the mean difference" from repeated measurement are less in US than in MRI. It is easy to change to a higher-frequency US transducer to obtain greater spatial resolution. The spatial resolution of US is much better than that of MRI if both examinations are performed with the most modern equipment. Furthermore, US can demonstrate the neovascularisation (Doppler) and the stiffness of the tissue (elastography) in tendinopathy.

In the lecture, the ultrasound typical findings of different mechanical and inflammatory tendinopathies are reviewed and completed with a live demonstration of ultrasound scan of a tendon.

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WEDNESDAY, 13 JUNE 2018

New drugs – new perspectives: clinical and regulatory issues concerning biosimilars

SP0024 AN UP-DATE ON BIOSIMILARS

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Biosimilars represent a new opportunity for lowering the cost of treatment with biological disease-modifying antirheumatic drugs (bDMARDs). Studies have demonstrated large inequities in the access to bDMARDs across countries and this inequity is related to economic parameters such as gross domestic product. Thus, reduced costs of bDMARDs should potentially lead to better treatment for more patients, especially in countries with low economy.

The regulatory agencies in Europe and in US have set up strict guidelines for approval of biosimilars which include extensive pre-clinical examinations (structure and functional characteristics) but less clinical data than for an originator product. The clinical part of this comparability exercise focuses on efficacy, safety, pharmacokinetics as well as immunogenicity.

Three biosimilars to adalimumab have also been approved but the patent of the reference product has not yet expired (expected to occur October 2018). (expected to occur October 2018). It is a growing acceptance about the use of these biosimilars, also in extrapolated indications when treatment are started or changed for medical reasons. Most rheumatologists will consider the biosimilars on the same level as originator products in these situations.

However, replacing an originator product by a biosimilar is more controversial, but is important because of the large cost-savings. Switching evidence is available from four different types of studies which will be discussed:

- Extension of phase 3 RCTs
- Switching within RCTs
- Real life data (eg from DANBIO)
- Randomising patients on stable long-term treatment

In the NOR-SWITCH trial – totally funded by the Norwegian government – 482 patients on stable treatment with the reference product infliximab across 6 indications (RA, SpA, PsA, UC, CD, PsO) were randomised to continued treatment with the reference product or switch to the biosimilar CT-P13; Jørgensen KK et al. *Lancet* 2017;389:2304–2316). The primary endpoint was occurrence of disease worsening, defined by the disease-specific composite measures or clinically significant worsening leading to a major change in treatment. Overall, disease worsening occurred in 26.2% of patients who continued treatment with the originator infliximab and in 29.6% of patients who switched to CT-P13. The adjusted treatment difference (95% CI) was –4.4% (–12.7–3.9) which was within the prespecified non-inferiority margin of –15%. The occurrence of adverse events, including infusion reactions, was similar across both groups. There were no differences between the two groups in secondary endpoints, including time to study drug discontinuation, remission rates, CRP levels, anti-drug antibody formation and drug trough levels. The extension study (not yet published) showed that switching from originator to biosimilar was not inferior to continued treatment with the biosimilar.

In conclusion, the NOR-SWITCH study demonstrated that switching to CT-P13 was not inferior to continued treatment with originator infliximab, adding to the increasing real-world evidence that switching from originator to biosimilar bDMARD is safe and efficacious.

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SP0025 SHARED DECISION MAKING IN SWITCHING TO BIOSIMILARS

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This presentation will focus on the speaker's experience of switching patients who are on an originator biologic therapy to a biosimilar, using a shared decision making approach. It will initially explore what constitutes shared decision making, why it is important when switching to biosimilars and the benefits of this approach.

The speaker will discuss how this change in therapy was achieved in practice when switching patients to both intravenous and subcutaneous biosimilars. There

will be a focus on the patient consultation itself, recognising patient anxiety and an exploration of why some patients declined to switch.

The speaker will share how loss of efficacy to the biosimilar was managed, and how this influenced the shared decision making approach.

Clinician's concerns will also be considered, specifically the inability to maintain pharmacovigilance (in not having sufficient nursing resources to add patients who had switched to a biosimilar to a national register). This is relevant to shared decision making as providing evidence and reassurance to patients regarding safety of biosimilars relies on this data collection.

The guidance referred to in this presentation is from NHS England, National Institute for Health and Care Excellence and the British Society for Rheumatology, so it has a UK focus. However, the main themes of the talk should be relevant to all audience members as it considers the opposing pressures on Rheumatology nurses to be change agents and make cost savings in implementing this switch to biosimilars. Whilst nurses also need to act as the patient advocate in ensuring shared decision making is a reality: that a face-to-face consultation takes place and that the patient can decline to switch and not feel penalised. The speaker will reflect on how the trust in her relationship with her patients was tested by this experience.

The main recommendation from this presentation is that rheumatology teams need to be proactive in managing this change and securing extra funding for nursing or pharmacy support. This 'invest to save' approach will enable appropriate consultation with patients to allow them to give informed consent to switch their therapy and feel supported whilst this switch takes place. It also enables maximum cost savings by ensuring the switch occurs quickly.

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SP0026 BIOSIMILARS – THE CHANGING VIEWS OF PARE'S MEMBER ORGANISATIONS

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After EULAR PARE's position paper "Biosimilars – what do patients need to consider" published in November 2015 more biosimilars for rheumatic diseases have been approved by EMA (European Medicine Agency), have entered the market in different European countries and more biosimilars will be marketed. New studies and data informing about the use of biosimilars, as well as feedback received from patient organisations and in particular from PARE organisations, have made it necessary to update PARE's 2015 position.

Biological therapies are enormous cost factors for the healthcare system and biological therapies have to be affordable, what is seen as difficult in various countries. But an optimal quality healthcare is enormously important for the individual patient (e.g. fewer sick days, less hospitalisation, less disabilities), prevents early retirement and thus saves costs and contributes to a country's economic and social system.

If so-called naïve patients should take a biologic, the less expensive biosimilar can be used, as long as there are no contraindications, the patient has been informed and the decision is based on a shared decision between rheumatologist and patient.

But transitioning users from an originator to a biosimilar is very controversial and seen critically by PARE's patient organisations. The talk will cover the changing views concerning extrapolation, one-time switch, multiple therapy switches, registries and the relevance of the application form for patients.

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Don't delay, connect today!

SP0027 DON'T DELAY, CONNECT TODAY – IMPLEMENTATION OF THE EULAR CAMPAIGN IN ROMANIA

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Background 22% of the population in Europe currently has, or had experienced "long-term muscle, bone and joint problems".¹ Early referral to a rheumatologist for appropriate diagnosis and treatment prevent structural damage, disability and decrease mortality.²

Objectives: To launch a patient oriented campaign in Romania in order to increase awareness of rheumatic musculoskeletal diseases (RMDs) – early