

## SAT0518 RA POPULATION CHARACTERISTICS IN INFORM, A LONGITUDINAL OBSERVATIONAL STUDY

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**Background:** InFoRM (Index for Rheumatoid Arthritis Measurement) is an ongoing multicenter, longitudinal, observational study of rheumatoid arthritis (RA). Enrolled patients contribute biological samples and clinical data to be used in the development of novel molecular tests.

**Objectives:** To describe the demographic and clinical characteristics of the InFoRM cohort at patients' initial visit.

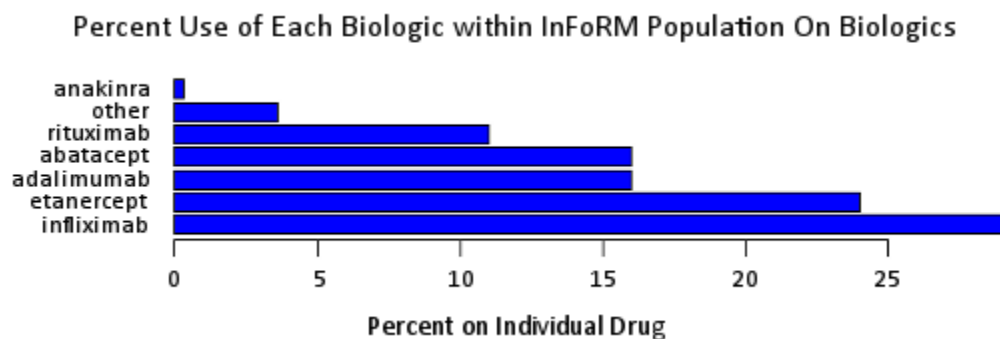
**Methods:** 15 community and 10 academic sites were recruited to enroll subjects into the InFoRM study. Subjects were required to be diagnosed with RA based on 1988 ACR criteria and between 18 and 90 years of age; sequential subjects were not required. Detailed clinical information was collected for each subject at 3 visits – baseline, ~3 months and ~6 months – including demographics, medications, co-morbidities and multiple measures of disease activity. Serum and RNA samples were collected at each visit; DNA at baseline. Central laboratory testing was performed for ESR (using Streck tubes), CRP, RF and anti-CCP (Roche Cobas). Population characteristics of the InFoRM cohort were compared to similar observational cohorts in North America including NDB, CORRONA, and QUEST-RA.

**Results:** >1200 subjects were enrolled in InFoRM over 8 months. The population was 74.1% Caucasian and 78.9% female; mean age  $58.1 \pm 13.7$  years and mean disease duration of  $14.6 \pm 11.8$  years (similar to subjects in NDB<sup>1</sup> (first observation (1998-2005): mean age  $58.5 \pm 13.1$  years, 92.7% Caucasian, 78% female, mean disease duration  $16.7 \pm 12.7$  years). The average DAS28ESR4 score in subjects was  $3.95 \pm 1.6$ , which is comparable to other large multicenter, observational studies such as CORRONA (3.7 to 3.8)<sup>2</sup> and QUEST-RA (USA centers only) 3.3<sup>3</sup>.

94% of subjects were taking  $\geq 1$  biologic and/or non-biologic DMARD, including 60% on a biologic; 34% were taking a steroid. Treatment strategy varied widely by site: The range of non-biologic DMARD use was 62 - 100%, biologic use 16 - 88% and steroid use 10 - 63%. The most commonly used biologic was infliximab followed by etanercept (see graph). Biologic use was higher in InFoRM than other reference populations: NDB 28% biologics at first enrollment (49% biologics at any point) and 46% steroids at first enrollment, QUEST-RA (USA only) 27.6% biologics and 60.1% steroids<sup>3</sup>.

Co-morbidities were reported in 83% of subjects, including hypertension (39%), osteoarthritis (34%), osteoporotic bone fractures (24%) and fibromyalgia (8%).

**Image / Graph:**



**Conclusion:** The InFoRM study has allowed us to create a large RA biobank with detailed clinical data in a short time. Simple inclusion/exclusion criteria resulted in a cohort in many ways similar to other

observational cohorts drawn from the North American RA population. We intend to use this resource for biomarker discovery and research on a range of clinical questions, including development of a multi-biomarker disease activity test.

**References:**

1. Frederick Wolfe, et al., *Arthritis Rheum.* 2007 Sep;56(9):2886-95.
2. Susan J. Lee et al., *J Rheumatol.* 2009 Aug;36(8):1611-7
3. Tuulikki Sokka et al., *Arthritis Res Ther.* 2009 Jan;11(1):R7

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