DNAlytics & RheumaKit in clinical trials

Many DMARDs developers are facing the issue of targeting the right patients. Either they are developer of new drugs, and have to prove more effective than the existing ones, or they experience (or fear) demands for increased efficacy from private or national health payers.

DNAlytics, the designer and owner of RheumaKit, bases its activities on a data mining technology platform. Based on this technology platform, DNAlytics covers the whole development of data-driven personalized medicine solutions, from R&D to market access.

We propose to DMARDS developers a support in the conduct of their trials, combining our pure data mining expertise with the appealing features of the RheumaKit.

In practice, we propose:
- To contribute to the design and writing of clinical protocols for all data-related matters and biopsy related matters
- To fully develop the study Statistical Analysis Plan (SAP)
- To set up the shipment and processing of the biopsies in order to
  - Acquire RheumaKit signature values
  - Generate a pathway-based analysis
- At the end of the trial, to apply the SAP, and to perform the data analysis including patient stratification

Depending on the sponsor strategy, the stratification could be considered early in the trial as a screening tool, or later as a pure stratification analysis, for example to identify differentiated response in various pathway-characterized subpopulations.

Ongoing theranostic developments

RA patients (all RA, not only those initially UA), receive methotrexate (MTX) as a 1st line treatment. MTX is only effective in 60% of the patients. When proven inefficient, a second line treatment based on biologicals DMARDS is initiated. Several exist, among which a few anti-TNF agents. All these treatments show a similar efficacy of around 60%, each effective on different sub-populations. There is thus a need for a more targeted treatment strategy.

The patented signature used by RheumaKit for undifferentiated arthritis diagnosis contains several genes involved in various metabolic pathways of primary importance in the field of Rheumatoid Arthritis: T and B Cells activation, TNF, Type 1 Interferon, Chromatin Remodelling, etc. These pathways are important either because they relate to underlying disease mechanisms, or because they a priori shed light on treatments efficacy. It is thus possible to get insight on these pathways based on the standard RheumaKit analysis (see figure).