FINDING THE OTHER 90 PERCENT:
Attracting Naïve Patients to RA Studies

A recent study by Tufts Center for the Study of Drug Development, based on a survey of 2,000 physicians and nurses primarily in the United States and Europe, found that 91% of physicians feel 'somewhat' or 'very' comfortable discussing the opportunity to participate in a clinical trial with patients, but actually refer less than 0.2% of their patients into clinical trials.[1] In conjunction, more than 80% of patients say they are willing to participate in clinical research studies, but only around 10% actually do so.[2] It is further reported that while 85% of patients are generally comfortable presenting any clinical research information they find to their doctor, only 17% have actually done so.[3] And what of those patients that are interested in participating in a clinical study only to find they are ineligible? When queried on next steps after finding out he/she did not qualify, 36% stopped looking for a clinical research study to participate in.[3] This latter fact is a staggering waste of potential when you consider that there are currently >130 planned or ongoing industry-sponsored Phase II-III rheumatoid arthritis (RA) studies to choose from (>210 when you consider any type of study sponsor).[4]

Considering the small proportion of patients actually participating in clinical studies, on the backdrop of what is probably the "busiest" competitive landscape of any indication, it is not surprising that RA studies are taking longer and/or requiring more sites to complete. It is also clear that there is a significant potential to attract more patients to participate in clinical trials. The big question is how does the industry achieve this? To answer this simply, we need to better utilize available resources and consider the impact of the eligibility criteria we introduce into our study protocols.

So what are the options open to us? The following two examples focus upon fully utilizing the data available to us:

- **Protocol eligibility criteria:** RA protocols vary widely with respect to the C-reactive protein (CRP) eligibility criterion. Analysis of CRP eligibility levels in RA studies listed in Citeline Trialtrove indicates a range of 3.0 - 30.0 mg/L. The level of CRP chosen for eligibility can have a dramatic effect on the available patient pool. For example, introducing a CRP eligibility criterion of ≥10 mg/L reduces the patient pool by approximately 80% whereas a level of ≥5 mg/L reduces the patient pool by approximately 62%5 - suddenly, your potential patient population has doubled. While it is obviously not quite that simple, it is evident that greater consideration during protocol development can significantly affect your ability to recruit patients in a crowded trial environment. As indicated by this CRP example, Covance is able to conduct indication-specific analyses, comparing eligibility criteria of protocols in the public domain and combining with our proprietary database of >70 million de-identified patients (>324,000 RA patients) in order to optimise eligibility criteria for individual protocols.
- **Identification of new investigators:** As an industry, we tend to return to the same investigators time and time again (even those that previously failed to meet expectations) and we are all vying for their attention. Given the crowded trial environment and the paucity of patients actually participating in clinical research, surely it makes sense to identify rheumatologists that are naïve to clinical research and provide them with training and support to make them successful investigators. In doing so, we gain access to an untapped patient population and these patients in turn gain the opportunity to access new therapies – a classic win/win. Within the U.S., by further utilizing the above referenced

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patient de-identified data, Covance has the ability to pinpoint indication-specific patient densities/hotspots aligned with clusters of treating physicians that are not active investigators. This subsequently offers the potential to identify new investigators as well as neighboring referral sites. Furthermore, patients utilizing the laboratory facilities of our parent company (LabCorp) are being offered the option of opting in to be contacted directly about participating in clinical trials. Already, within the infancy of this initiative, over 100,000 patients have opted in, of which more than 700 are RA patients.

It is evident that there is a significant research effort being targeted towards the treatment of RA. However, delays in study recruitment ultimately lead to delays in getting newer therapies to patients. It is, therefore, also evident that we cannot run RA studies like we did in the past. As an industry, we need to attract the >90% of patients who, for whatever reason, do not currently participate in clinical trials. RA affects about 1% of the world population.6 Together, these statistics equate to approximately 67 million RA patients that do not participate in clinical studies – think about that over your next coffee break.

1. *Poor Physician and Nurse Engagement Contributes to Low Patient Recruitment Rates. Impact Report, Volume 19, Number 1, January/February 2017*
2. *BBK Healthcare, Inc./Harris Interactive, "The Will & Why Survey." Reinventing Patient Recruitment: Revolutionary Ideas for Clinical Trials Success, (Gower Publishing, Surrey, UK, 2006).*
3. *Report on the Decision to Participate. 2015 PERCEPTIONS & INSIGHTS STUDY. Center for Information and Study on Clinical Research Participation (CISCRP).*
4. *Citeline Trialtrove*
5. *LabCorp data*
6. *Gibofsky A. Overview of epidemiology, pathophysiology, and diagnosis of rheumatoid arthritis. Am J Manag Care 2012;18:S295-302.*

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