NEWMEDS announces new drug database

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In a remarkable and unprecedented collaboration NEWMEDS (Novel Methods leading to NeW MEdications in Depression and Schizophrenia) have pooled resources to bring together data of 23,401 anonymized patients from 67 trials on 11 compounds in over 25 countries to form the single largest database of clinical trial data ever amassed in psychiatric research.

It is widely recognized that despite tremendous growth in biomedical knowledge, the deciphering of human genome and almost daily round of discoveries – the rate of development of new drugs has been slow. This is especially true in psychiatric disorders. One barrier to development has been the competitive relationship between rival companies and the other has been the limited exchange of science across the industry-academic divide.

In September 2009, the Innovative Medicines Initiative (a Joint Undertaking between EU and EFPIA) launched a unique collaboration especially to address this issue in the area of psychiatric drug development: NEWMEDS (Novel Methods leading to NeW MEdications in Depression and Schizophrenia). NEWMEDS, led collaboratively by Dr. Tine Bryan Stensbøl (H. Lundbeck A/S) and Professor Shitij Kapur (Institute of Psychiatry, King's College London) brings together seven academic research institutions, nine major pharmaceutical companies and three small and medium-sized enterprises into one consortium to overcome three major bottlenecks in developing models and methods in drug discovery as they relate to schizophrenia and depression. These bottlenecks are lack of accurate animal models to

guide drug discovery, lack of tools and tests in healthy volunteers that can provide early indication of efficacy; and reliance on a clinical trial methodology that has remained rather unchanged for 50 years.

To identify how modern clinical trials might be improved – the companies needed to collaborate to share their data and devise new ways of predicting which treatment is likely to work for which patient (individualized medicine) rather than using the standard trial-and-error for everyone. NEWMEDS is taking on these challenges in Schizophrenia and Depression.

Dr. Tine Bryan Stensbøl, the industry lead and coordinator of NEWMEDS states "the pharmaceutical industry model where each company in isolation tries to solve precompetitive problems is being challenged by NEWMEDS. We have successfully identified a precompetitive match between competing companies and strong academic centres in Europe. Data from clinical trials run by individual EFPIA companies are brought together for new areas of research relevant not only to academic research but also to EFPIA going forward." Prof. Jonathan Rabinowitz (Bar Ilan University, Israel), who is leading the analysis of the Schizophrenia data says "for 50 years we have been doing trials the same way – with a standard placebo or active control, for 4-6 weeks and using the same statistical approaches. By bringing together this large dataset we have a unique opportunity to see whether patients who get better on placebo – for the first time, and we have over 2,000 of them – are somehow different. We will be able to identify if trials could be smaller, faster and can decrease exposure of patients to experimental medications."

In the area of Depression, the NEWMEDS partnership aims to determine why some patients respond to one kind of antidepressants, and others do not. While these efforts have been tried by individual academic groups or by individual industry – they have usually fallen

short due to limited numbers. By pooling together the resources of public sector projects (GENDEP and GenPod) with trials from 3 pharmaceutical companies – NEWMEDS has brought together data on the genetics and clinical response in over 1800 patients. This now becomes the world's largest resource of well characterized patients with depression, treated with different antidepressants where one may ask the question of who responds best to which. Professor Peter McGuffin (Institute of Psychiatry, King's College London) comments: "NEWMEDS has facilitated an unprecedented collaboration between academia and industry on the pharmacogenetics of depression that finally gives us a big enough, powerful enough sample to address how genetics influences antidepressant response. This could lead to changes in the way we select patients for trials, and in the long run how we select treatments for individuals."

Prof. Kapur who has been the overall academic leader of this NEWMEDS partnership commented "the landscape of drug development and scientific discovery is changing. After pioneering examples in the field of genetics where sharing data has led to new discoveries – we wanted to see how this could be done in the clinical arena. NEWMEDS is the first large scale example of such collaboration between industry and academia in this field in psychiatry. Hopefully, this will be one step that will help reverse the drought of new medications in psychiatry."

How did this change in culture and practice come about? Dr. Michel Goldman, Executive Director of the IMI programme comments: "Acting as a neutral third party, the Innovative Medicines Initiative supports and facilitates the collaboration between public and private partners. The achievements of the NEWMEDS project underline the success of this innovative approach. The academic community will greatly benefit from the partnership, as the exceptionally large and valuable database on schizophrenia will be made available to all participants in the project.

IMI has already launched 15 collaborative projects in different disease areas. In October, IMI launched another Call for proposals that will result in a new set of research and training projects."

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