aspects of functioning and their related neural systems. These could represent within- or trans-diagnostic dimensions that provide more homogeneous groupings for research in new drug development and clinical trials.

**Speaker 2: Shitij Kapur, UK**

Title: NEWMEDS Innovative Medicine Initiative – Accomplishments and Lessons from a Pre-Competitive Consortium.

Shitij Kapur, MBBS, PhD, FMedSci

King’s College London and the Institute of Psychiatry, Psychology and Neuroscience

There have been remarkable advances in genetics, molecular biology and imaging technologies and every year nearly 15,000 articles relating to schizophrenia and depression are published. Despite these notable advances, there have been few truly innovative new medications that have made it to the clinic. The EU Innovative Medicines Initiative attempts to address this gap through a series of consortia.

NEWMEDS was one of the first (initial application 2008) initiatives and it identified three major challenges: i) a lack of pathophysiology-accurate animal models guiding the drug discovery; ii) a lack of tools and tests in healthy volunteers that can provide early indication of efficacy; and iii) the reliance of clinical trials on symptom-based DSM-categories which inevitably lead to biologically heterogeneous groups of patients. To overcome these limitations, NEWMEDS brought together a consortium of expertise from seven leading universities, two SMEs, and ten EFPIA partners. The purpose of the project was not to develop new drugs – but to develop new methods. Therefore, the focus was on new “pre-competitive” insights, methodologies and analytical methods the NEWMEDS.

Over its lifetime the NEWMEDS consortium: a) developed standardised animal models that focus on reliable cross-species endophenotypes (e.g. cognitive function) based on touch-screen technology which is analogous to what is used in clinical testing; b) develop MRI and PET based paradigms which may serve as early or surrogate markers to provide guidance for drug development – compatible with cross-species translation and developed new machine-learning methods of image analysis (PiPR); c) examined a set of genetic abnormalities (CNVs) closely linked with Schizophrenia (15q11, 15q13), validated their impact on human populations and developed homologous animal models that are now available to others; d) amassed the largest depression treatment cohort to look for pharmacogenetic biomarkers to stratify response to antidepressant treatments, but, did not find major stratifiers – however this exercise did lead to a simple tool for assessing the clinical utility of any future biomarkers (www.depresstoolstools.org); and e) by bringing together the largest multi-industry clinical database in Schizophrenia and Depression – identified how trials could be shorter and more efficient. But also identified how trials inadvertently enrol duplicate patients and built a potential solution for this problem (DupCheck - www.dupcheck.org).

While the NEWMEDS consortium itself has come to an end it provided several important lessons about the organisation of these consortia: especially the importance of long-term commitment, consistency of personnel involved, the necessity of focussed objectives and procedural flexibility. The IMI continues to be using this mechanism for a range of projects in Autism (EU-AIMS), Pain (EuroPain) and Cognition (PharmaCog).

Drug development in Psychiatry still remains a challenge. Since 2008 when this project was started, several major companies have disinvested from psychiatry highlighting the complexity of challenges in this area. Given this, such “pre-competitive” consortia are even critical to make the advances to make the field attractive enough for commercial interests to then explore them.

The talk will provide more details about NEWMEDS, lessons learnt and some thoughts about the challenges and solutions for drug development in Psychiatry.

**Speaker 3: Tetsuya Suhara, Japan**

Title: Japan PPPs Perspective

Abstract

CIP is a leading organization in the field of CNS drugs. As Public Private Partnerships for CNS drug innovation activity, we have discussed in Japan on three topics 1. Imaging biomarkers, 2. Stratification factors, 3. How to share the clinical study data with Academia, Industry and Regulators. Working group 1 focused on imaging biomarkers those can be useful for decision making in drug development. The idea of three pillars to ensure the steps to get clinical POC has been reported form Pfizer. Pillar 1 means the evidence reaching the target site, pillar 2 means the evidence of binding to the pharmacological target and pillar 3 means the evidence of pharmacological action in the brain. The imaging biomarker can be used whether the candidate drug fulfill pillar 2, using receptor occupancy. Using common terminology to express the developing stage would be useful in PPP setting, since different company used different terminology in each company. During our discussion, we thought more precise classification would be needed to explain the stage of the candidate drugs. We propose tier as an alternative of pillar, [Tier 1;target exposure, Tier 2; target binding/engagement, Tier 3a; mechanism-related change, Tier 3b; functional modulation, Tier 4; patient stratification, Tier 5 Disease-related change]. Future needs of imaging biomarkers will be discussed in relation to the various imaging methods. Working group 2 focused stratification factors using the data on randomized double-blind clinical trials of conventional antidepressants vs placebo that have been conducted so far in Japan. Working group 3 focused how to share the clinical study data with Academia. Although majority of the pharmaceutical companies have disclosed not only an initiation/completion of their sponsored clinical trials but also the results through the public domain like clinical trial. gov., the details of the disclosed data have been limited. Working group 3 aimed to create a system to construct a database which unifies all clinical data obtained in the sponsored clinical studies in order to facilitate the pharmaceutical products of the next-generation.

**CP03: Depression**

**Speaker: George Papakostas, USA and Hong-Jin Jeon, Republic of Korea**

Abstract

Major Depressive Disorder (MDD) is a serious, debilitating, life-shortening illness that affects many persons of all ages and backgrounds. All FDA-approved antidepressants used as monotherapies have shown only modest benefits. In fact, in acute (6–8 week) studies, typically with relatively uncomplicated, non-chronic forms of MDD, remission rates range between remission rates range between 30.0–35.0%. To make matters worse, as currently delivered, none of these pharmacologic and