This poster presents a model of collaboration between a CNS-oriented CRO and investigators in academic centers. The following is a summary of several trials which have already resulted in publications or are about to be published in prestigious international journals.

**A randomized controlled trial of allopurinol vs. placebo added on to antipsychotics in patients with schizophrenia**

*Funded by the Stanley Medical Foundation*

**Introduction:**
An emerging body of evidence supports a purinergic hypothesis for psychosis (Ferre, 1997; Lara and Souza, 2008). Adenosine agonists have been shown to have properties similar to those of dopamine antagonists. Increased adenosinergic transmission has been demonstrated to reduce the affinity of dopamine agonists for dopamine receptors. Two studies (Akhondzadeh et al., 2005; Beaumier, et al., 2005), and one unpublished (Dickerson et al., submitted) double-blind, randomized, placebo-controlled trials have showed improvements in the allopurinol groups vs. placebo groups. These empirical data, together with the theoretical and basic science background cited, provide the impetus for this proposed study.

**Methods:**
An 8-week Randomized Controlled Trial (RCT) of allopurinol vs. placebo added to anti-psychotic medications in 248 patients with schizophrenia.

**Results:**
Both the allopurinol and the placebo group showed improvement in PANSS scores and in CGL and cognitive measures. However, no difference was observed between groups in primary or secondary outcome measurements. In summary, the current findings do not support a clinical role for allopurinol as a treatment for schizophrenia.

**A randomized controlled trial of allopurinol vs. placebo as add-on to mood stabilizers and/or antipsychotics in manic bipolar patients**

*Funded by the Stanley Medical Foundation*

**Introduction:**
The trial hypothesis was that perturbations are implicated in the pathophysiology of psychosis (see above for detail description).

**Methods:**
The current study was a large 6-week trial of allopurinol as add-on therapy to antipsychotics and/or mood stabilizers in acute mania. YMRS, PANSS, and CGI-BP were used as assessment instruments.

**Results:**
Allopurinol conferred no benefit compared to placebo for the clinical symptoms of mania. We observed neither adverse effects nor worsening of clinical symptoms in the treatment group.

**Aspirin, minocycline, or pramipexole vs. placebo as add-on to antipsychotics in patients with Schizophrenia**

*Funded by the Stanley Medical Foundation*

**Introduction:**
The hypothesis that schizophrenia is associated with an inflammatory process has both biological plausibility and epidemiological support. A large number of small N trials have indicated that anti-inflammatory drugs might benefit symptoms of schizophrenia. Similarly, DA agonists like Pramipexole have been shown to benefit non-psychotic symptoms of schizophrenia.

**Methods:**
An RCT of 16 weeks which included 400 patients.

**Results:**
Individual comparisons between each drug and placebo showed trends for significance for aspirin but not for the other 2 drugs. Aspirin might exert a beneficial effect either as an anti-inflammatory or via a direct effect on brain prostaglandins activity.

**A randomized trial administering raloxifene vs. placebo as add-on to antipsychotics in post menopausal patients with schizophrenia**

**Introduction:**
Epidemiological evidence shows a potentially protective role for estrogen in women with schizophrenia. The objective of the study is to evaluate the efficacy of raloxifene compared to placebo, as add-on to antipsychotics in the treatment of postmenopausal patients with schizophrenia.

**Methods:**
Some studies shows that women receiving 120 mg had a significant improvement in the PANSS total score, and those receiving raloxifene 60mg showed a significant reduction in PANSS positive, negative and general symptoms. Results are currently being analyzed.

**SWITCH: Early switching strategy for non-responders schizophrenics**

*Funded by the German government*

This trial investigates how early should a patient who does not respond to an antipsychotic be switched to another antipsychotic. The study should also investigate whether a change of medication in non-responders to a two-weeks antipsychotic drug trial is more effective than continued treatment with the same antipsychotic. Hypothesis: Non-responders who are switched at 2 weeks to another antipsychotic show higher degree of symptom reduction (change of total score of Positive and Negative Syndrome Scale, PANSS) at week 8.

**Outcomes:**
Primary efficacy and point percentage of patients in remission at week 8 (comparison of combined switch groups and combined non-switch groups). The study is currently recruiting patients.

**OPTiMiSE: Optimization of Treatment of Schizophrenia in Europe**

*Funded by the FP7 European Community program*

http://www.optimisetal.eu/ (Library)

This is an FP7 initiative funded by the European community in which the leading European academic centers participate. This study will focus on two goals: optimizing current treatments in schizophrenia and understanding the pathophysiology of the disease taking advantage of imaging techniques. It is expected that the project will lead to evidence that is directly applicable to treatment guidelines, and will identify potential mechanisms for new drug development. Patients are currently being recruited for this study.

**A randomized, double-blind, valnoctamide, placebo and risperidone-controlled trial in bipolar manic patients**

Valnoctamide is a mood stabilizer form the anti-epileptic family hypothesized to be less thioridazine-like than similar drugs in its class. Hence if effective, it might be of use in pregnant individuals who need maintenance treatment for bipolar illness. The objective of the study is to evaluate the efficacy of valnoctamide compared to placebo in the treatment of patients with an acute manic or mixed episode.

**Endpoints:**
Mean change from baseline in Young Mania Rating Scale (YMRS) score in the valnoctamide group compared to placebo and time to discontinuation. The study will start recruiting patients in the next few weeks.

**CTR** (TGD) presents a model of academic-CRO cooperation leading to better research and education in psychiatry and to scientific publications. CTR (TGD) offers CME courses in cooperation with the Craiova University, and PhD programs in Neuroscience in cooperation with Leyden University