PSY-PGx – A New Intervention for Implementation of Pharmacogenetics in Psychiatry: Progress and Challenges

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Background

- Genetic heterogeneity is one of the reasons for high variability in response to psychopharmacological treatment as well as adverse effects of it
- Pharmacogenetic testing on genes encoding drug-metabolizing enzymes might facilitate the dosing process
- PSY-PGx Consortium (www.psy-pgx.org) funded by European Union's Horizon 2020 Program
- First non-industry sponsored multi-center large scale randomized clinical study
- Start of Funding: March 2021

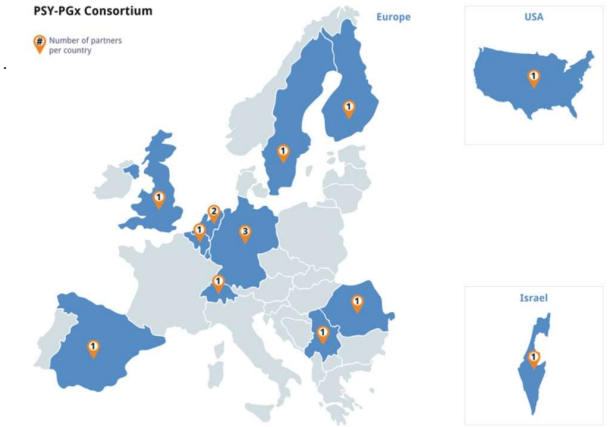

Figure 1. The International PSY-PGx Consortium

Aims

1. Identify real-world relationships between pharmacogenetic data and clinical outcome in patients by assessing the Finnish and UK biobanks
2. Clinical study to compare outcome between individualized pharmacotherapy and treatment as usual
3. Collect further phenotypic data that might have effects on medication response
4. Machine learning to refine the prescription algorithm
5. Establish a PSY-PGx DNA biobank and a cellular biobank for a pharmacogenetic research infrastructure

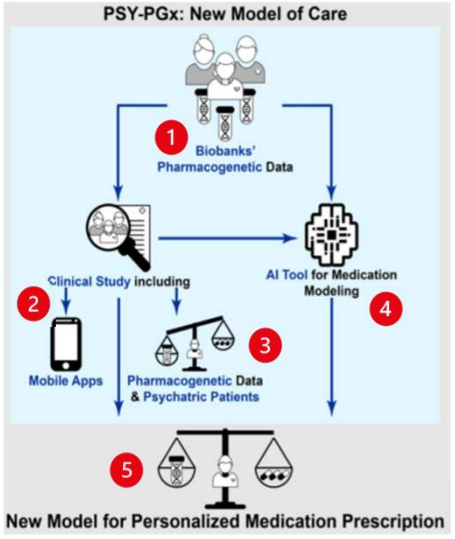

Figure 2. PSY-PGx Work Program

Main Achievements

Biobank Assessment

- Proposals were formulated, submitted and approved by the Finnish and UK biobanks
- Legal agreements to transfer data are being finalized

Clinical Study

- Successful pilot genotyping in Bonn
- Protocol of clinical study finalized, submitted to 5 out of 9 sites and approved
- IT Infrastructure works as intended

Main Challenges

Biobank Assessment

- Lengthy process to obtain biobank data

Clinical Study

- Different regulations in different countries, even within the EU, regarding classification as Clinical Study vs. Clinical Trial, EU Centralized Procedure installed, large effects on costs and time
- Legal agreements time-consuming (Consortium Agreement, Data Transfer Agreements, Material Transfer Agreements, Clinical Trial Agreements)
- US site needs to be compliant with EU data protection regulations

Conclusion and Outlook

- Conducting a multi-center, international pharmacogenetic Clinical Study is challenging due to different legal frameworks
- Current focus is on recruitment and obtaining biobank data
- Further progress of the project to be presented

Conflicts of interest: None

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