

Methodology For Evaluating the REMS Programs for Psychiatric Medications

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Background

- Risk Evaluation and Mitigation Strategy (REMS) program
 - Helps: "Ensure the benefits of the medication outweigh its risks"
 - Focus on preventing, monitoring, and/or managing a specific serious risk
 - FDA determines the need for a REMS for a medication
 - Medication companies develop REMS programs, FDA reviews and approves program
- Elements to Assure Safe Use (ETASU)
 - Required medical or education interventions or other actions by healthcare professionals prior to prescribing or dispensing the medication
 - Some actions may also be required in order for the patient to continue on treatment

Examples of ETASU

- Certification or specialized training of healthcare professionals who prescribe the medication
- Certification of pharmacies or other dispensers of the medication
- Dispensing/administration of medication in limited setting
- Dispensing/administration of medication only with evidence of safe-use conditions
- Each patient using the medication is subject to certain monitoring
- Enrollment of treated patients in registries

Project Goal

- To understand healthcare provider perspectives regarding the value, access, and burden for the REMS for specific psychiatric medications and provide recommendations to improve patient access while ensuring safe medication use and limiting health professional impact

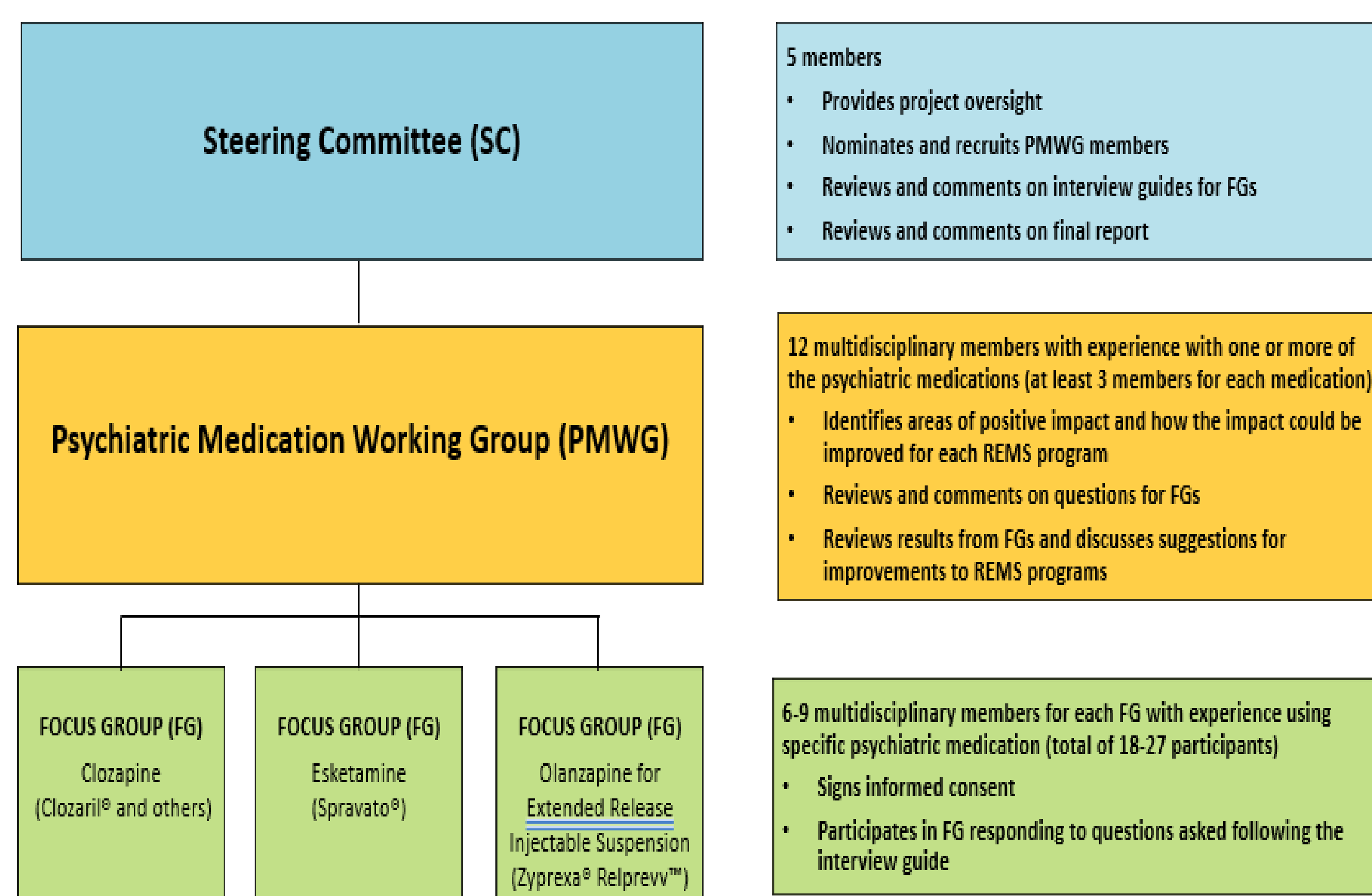
Objectives

- Create a Steering Committee to guide the research
- Convene a Psychiatric Medication Working Group (PMWG) to identify areas of positive impact and how the impact could be improved for each REMS program
- Elicit stakeholder perspectives on the Elements to Assure Safe Use (ETASU) for selected psychiatric medications through focus group interviews (FGIs)
- Summarize the findings for REMS ETASU for selected psychiatric medications

REMS Programs for Inclusion

	REMS Approved	Last Updated	ETASU
Esketamine (Spravato®)	3/5/19	1/03/2022	Yes
Olanzapine for Extended Release Injectable Suspension (Zyprexa® Relprevv™)	12/11/09	4/28/2021	Yes
Clozapine (Clozaril®)	9/15/15	11/10/2021	Yes

Roles and Activities of Project Participants



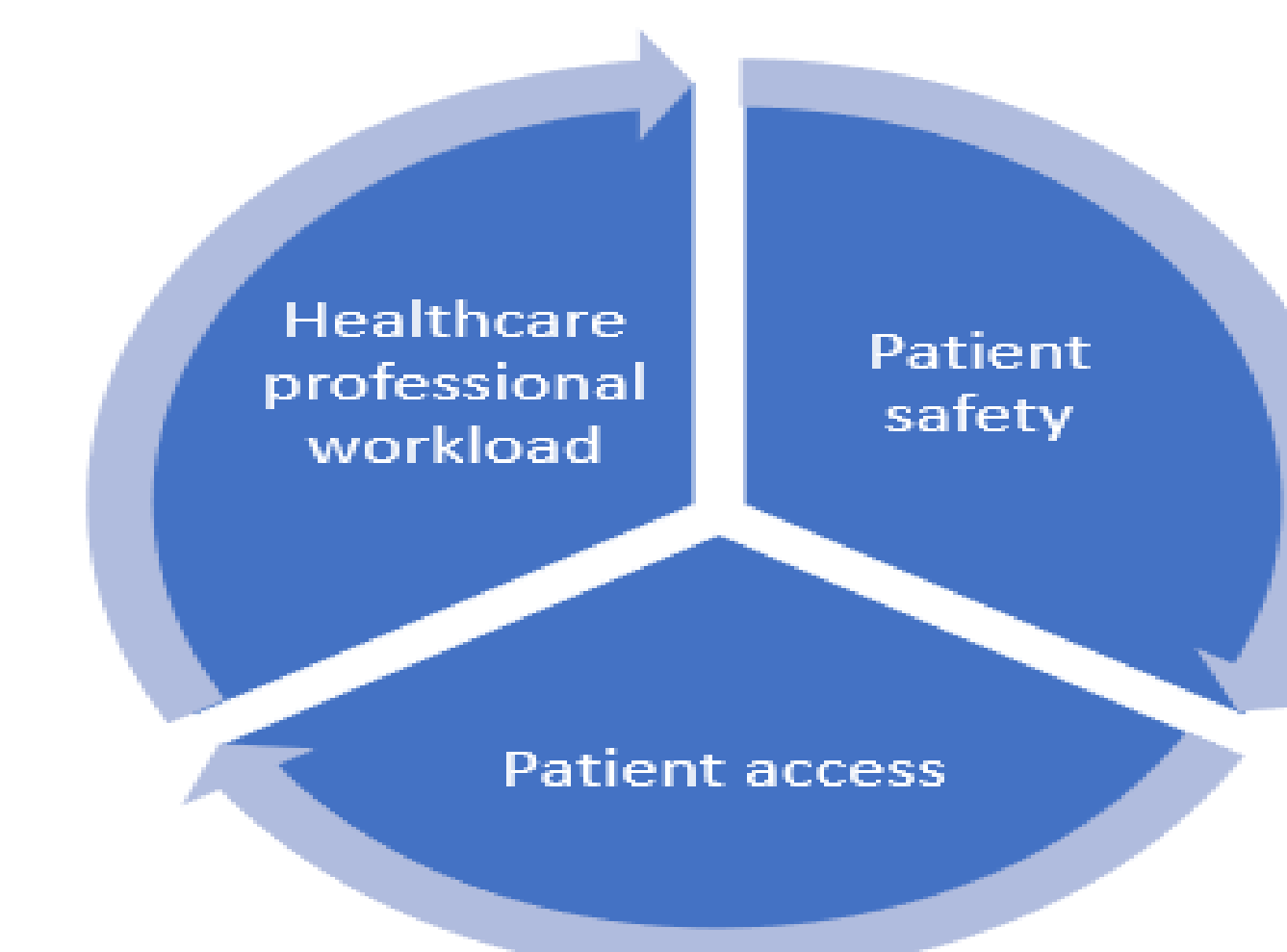
Participants

Participant Group	Details on Groups
Steering Committee	5-member group with representatives from National Association of State Mental Health Program Directors (NASMHPD), National Council for Behavioral Health, National Alliance on Mental Illness, Treatment Research Program (TRP) at the Maryland Psychiatric Research Center (MPRC) and Department of Psychiatry at the University of Maryland School of Medicine
Psychiatric Medication Working Group (PMWG)	Professional organizations nominated individuals for the PMWG
Focus Group Participants	Identified by PMWG to participate in one of three focus groups held between July and August of 2021

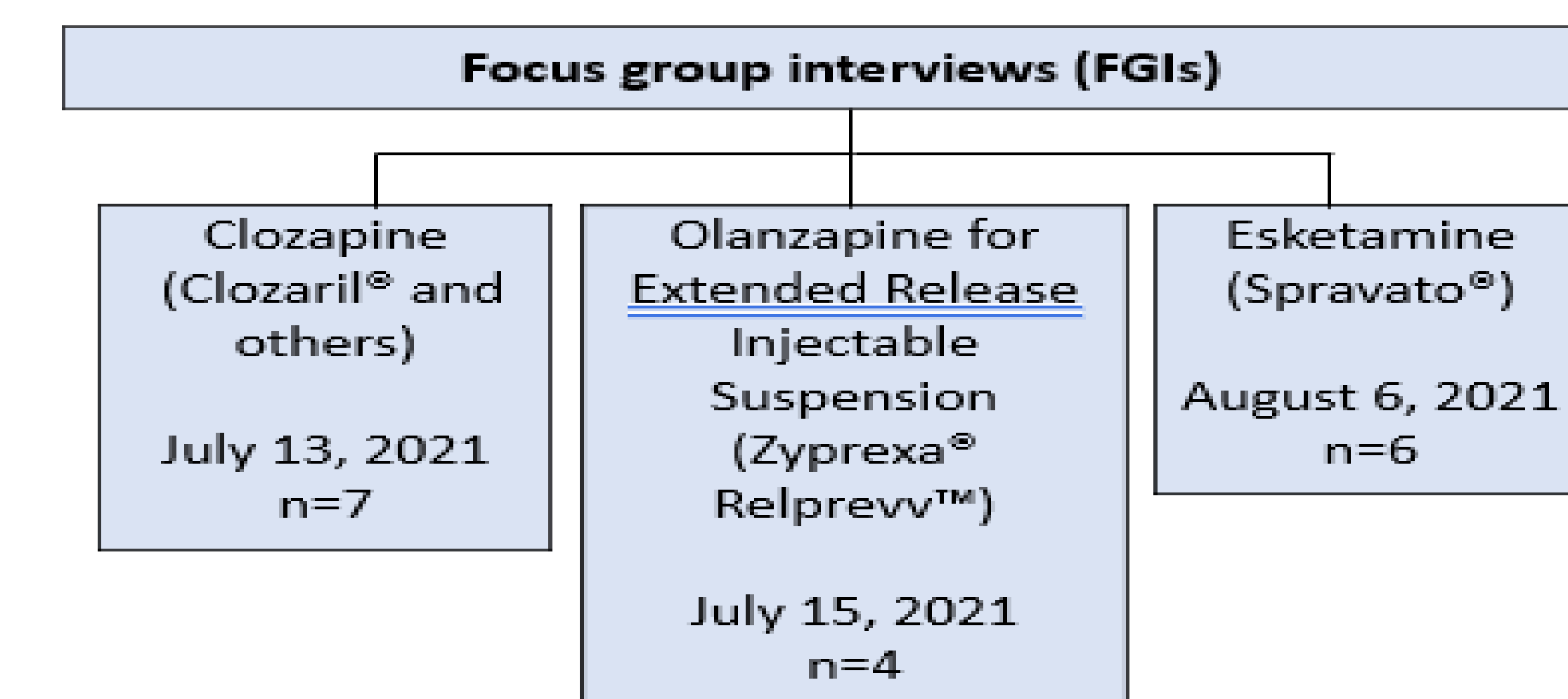
Discussions with SC and PMWG

- Identification of areas of positive impact and how the impact could be improved for each REMS program
- SC, PMWG, and FDA co-created the Facilitator's Guide
 - Contained details on how to conduct the focus groups
 - List of questions specific to the selected psychiatric medication

Framework for Interview Questions



Focus Group Interviews (FGIs)



Qualitative Analysis

- Focus groups were recorded and transcribed independently by two researchers
- Transcripts were assigned into one or more codes or subcodes
- Coded text was input into NVivo® software to identify positive aspects for each REMS program in addition to suggestions for improvement
- Coded data was sorted and collated into themes
- Themes: Significant concepts that link substantial portions of the data together
- Representative quotes for each theme were chosen independently by two researchers

References

- <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>