

# ***How do I know what medicine to choose??***

New approaches to studying medication treatment for children with ADHD and autism

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# Speaker Disclosures

- I have no financial disclosures, and no associations with pharmaceutical companies
- Psychotropic medications, both FDA approved and off-label will be discussed

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# So what do we know about ADHD in kids with autism??

- Lots of kids struggle with symptoms
- Hyperactivity & impulsivity → safety problems
- Hyperactivity & inattention → learning challenges
- Behavioral treatments often not enough
- ADHD medicines work well in kids without ASD

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# ASD + ADHD + Medications

Methylphenidate  
(Ritalin)

↓ hyperactivity  
?↓ inattention

4 Studies, each 1-2 weeks long  
Evidence: low to very low quality

Mixed  
amphetamine salts  
(Adderall)

Atomoxetine  
(Strattera)

↓ hyperactivity  
↓ inattention

4 Studies, each 6-10 weeks long  
Evidence: low to very low quality

Guanfacine

↓ hyperactivity

1 study, 8 weeks long  
Evidence: very low quality

Atypical  
antipsychotics

↓ hyperactivity

5 studies (risperidone, aripiprazole)  
Evidence: low to very low quality

# So what is a clinician to do??

- What medicine?
- What dose?
- When to try a different medicine?
- How to advise families?



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# PCORI = Patient Centered Outcomes Research Institute

- Independent, nonprofit research organization
- Authorized by Congress in 2010
- 2019 reauthorization – additional research priorities including Intellectual & Developmental Disabilities
- Aims to empower patients with “actionable information about their health and healthcare choices”
- Patients “at the table” throughout the research process
- Focus on outcomes that matter to patients

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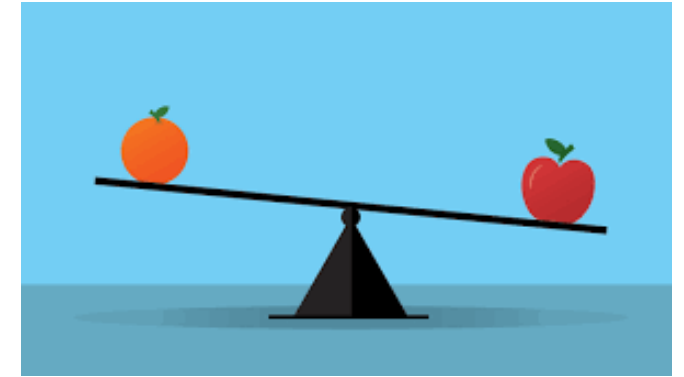


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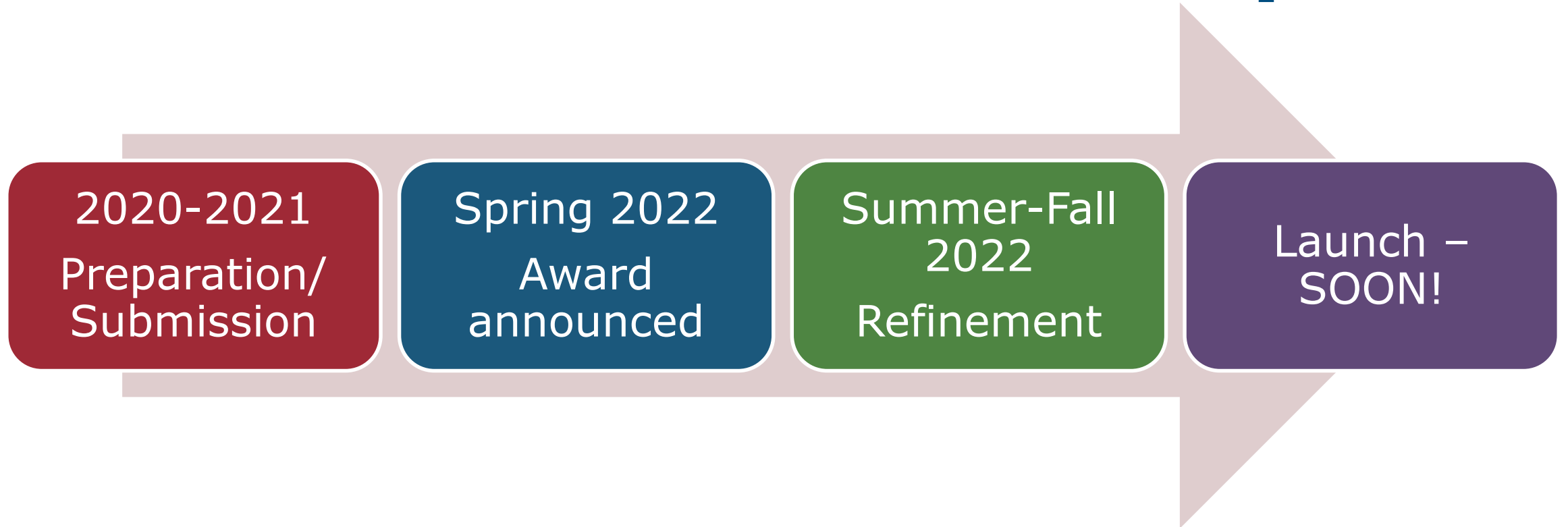
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# Comparative Clinical Effective Research (CER)

- Main type of research funded by PCORI
- Compares 2 or more medical treatments, services, or health practices
- Help patients/families know whether some approaches work better than others
- Help patients & others make better informed decisions



# Autism Care Network Proposal



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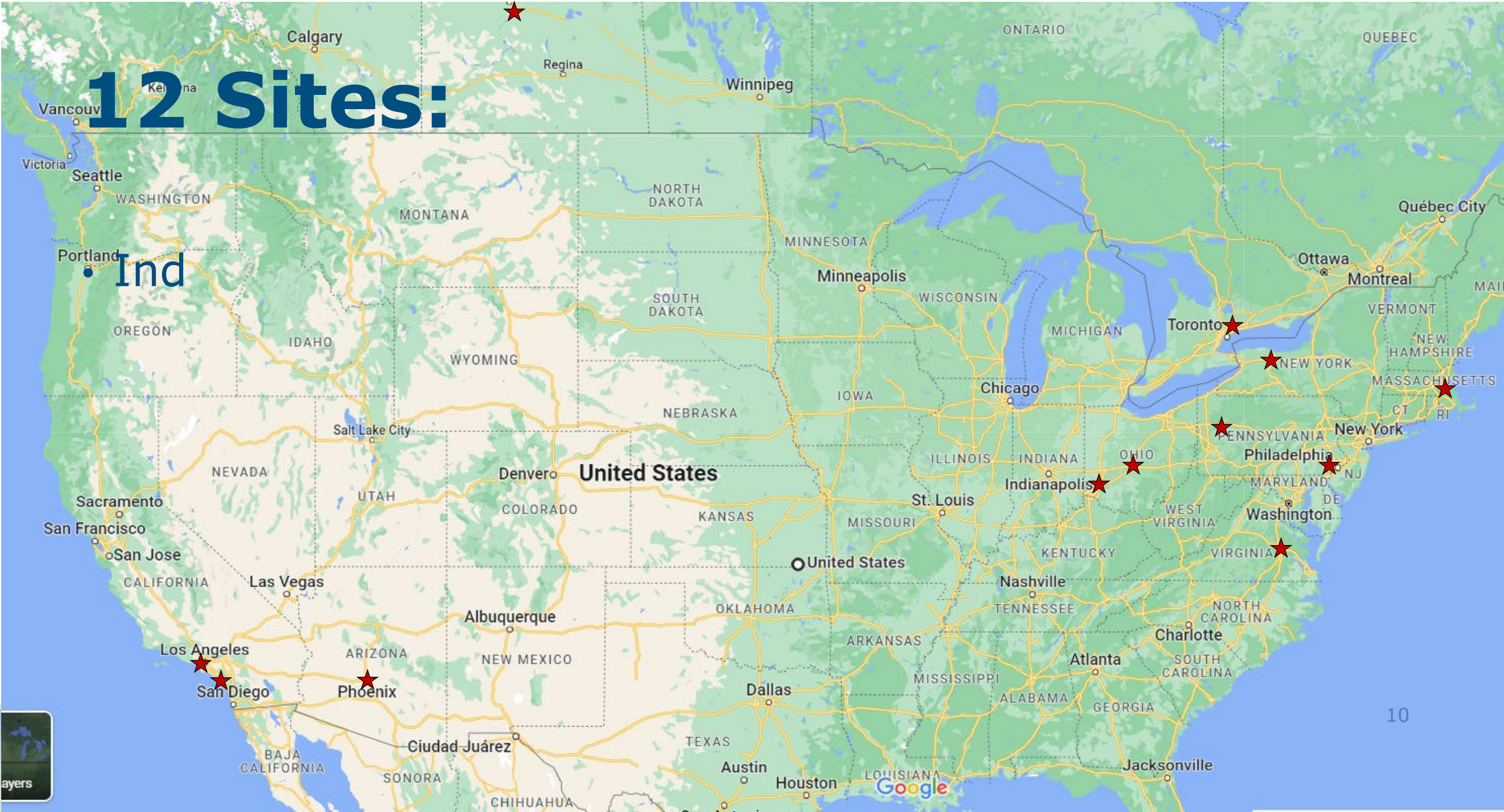
# Pragmatic Trial

- Test effectiveness of an intervention to improve health
- Conducted in:
  - real-world clinical practice setting
  - with typical patients
  - by qualified clinicians



# 12 Sites:

Ind



# Pragmatic Clinical Trial:

Intended to closely follow current practice



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## Aims:

1. Determine whether one type of stimulant medication is more effective than the other (methylphenidate vs. amphetamine)
2. Determine whether there is a significant difference between stimulants and alpha-agonist medication in children who did not receive satisfactory benefit from the first medication prescribed
3. Identify how parents make decisions to continue / not continue medication
4. Examine “moderators” of treatment response (age, gender, co-occurring conditions)

# Potential Participants



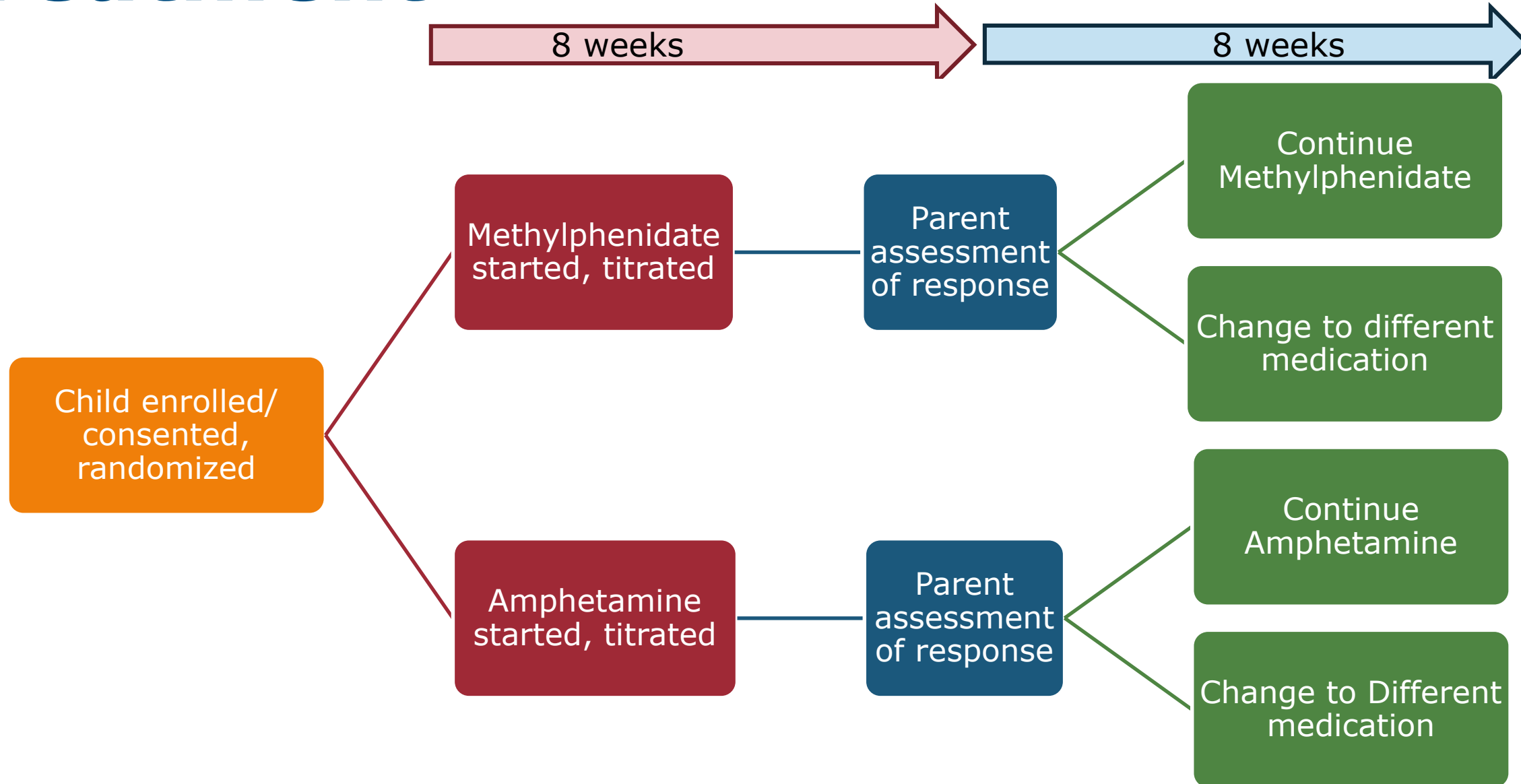
## Inclusion Criteria

- Age 4-17 years.
- 1.-Confirmed diagnoses of ASD + ADHD
- 2.-Ability to consistently take medication
- 3.-Consistent reporter (e.g., parent) who spends regular time with the child.
- 4.Other medications permitted if dose stable for  $\geq 4$  weeks with no plans for a dose change during the study.

## Exclusion Criteria

- History with more than one prior trial of an ADHD medication.
- 1.-Less than 4 weeks since last ADHD medication was taken.
- 2.-Any other risk factor that might prevent them from safely taking the study medications.

# Treatment



# Rochester Plans

- Recruitment starting spring, 2023
- ~12 patients/year
- Identify patients through:
  - Clinic visits
  - DBP research registry
  - Social media (join our DBP Facebook Page!)



# Rochester Study Team

- **Lynn Cole** – Primary Investigator
- **Emily Wagner** – Study Coordinator (missing pic)
- **Melissa Ryan** – investigator
- **Johanna Stump-Siembor** – Investigator
- **Claudia Perez** – Consulting study coordinator



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# Questions? Need more Information??

Contact our study coordinator:

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**THANK YOU!**

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