



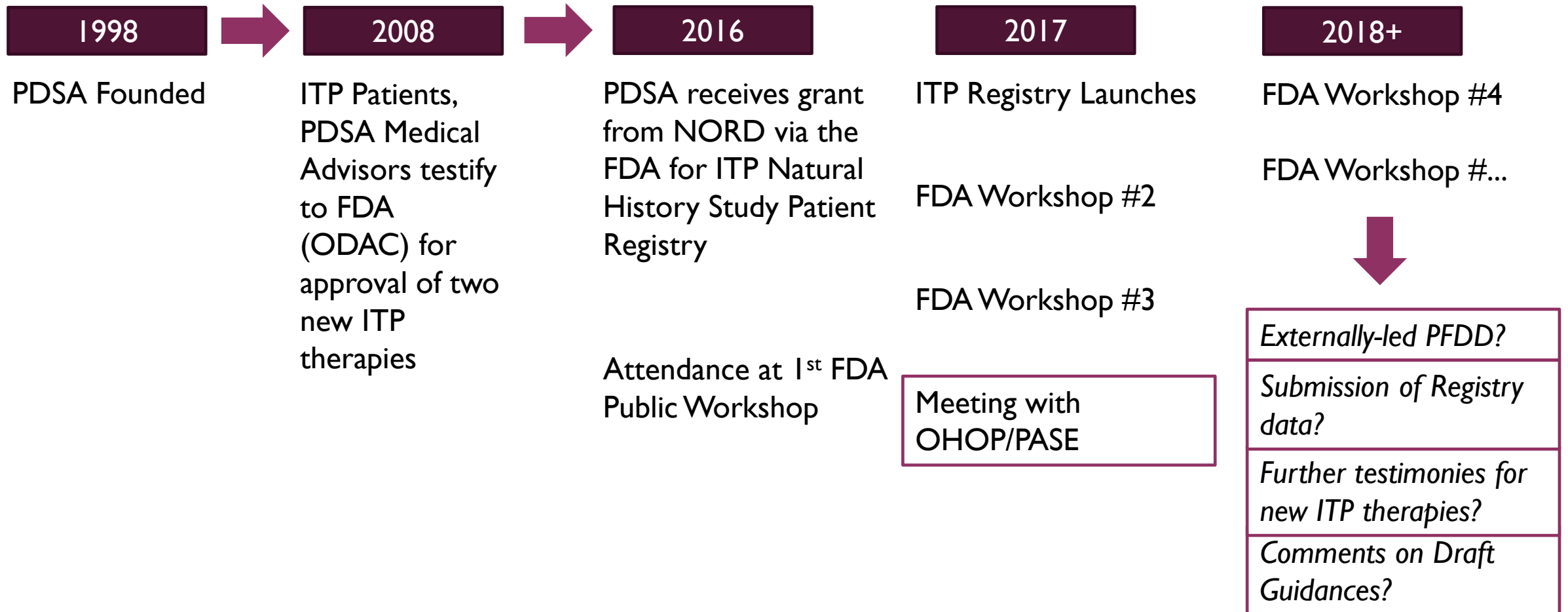
Platelet
Disorder
Support
Association



Empowering ITP Patients

Education. Advocacy. Research. Support.

ENGAGING WITH THE FDA



PLANNING YOUR MEETING

1. INVOLVE KEY OPINION LEADERS: patients and caregivers, patient advocacy group, physicians, researchers
2. CLEARLY ESTABLISH GOALS:
 1. Educate the FDA on the most significant symptoms, current treatment side effects, burden of disease, and impact of condition on daily life.
 2. Ensure that the patient voice is included in providing guidance and advancing science.
 3. Serve as a comprehensive resource on the patient experience to provide input and guidance in new drug development research moving forward.
3. DEVELOP YOUR ASK: PRIORITIZE THE UNMET NEEDS OF PATIENT POPULATION
4. PROVIDE PATIENT EXPERIENCE DATA

TAKE-AWAYS: BENEFITS OF COLLABORATING WITH THE FDA

“Meetings are greatly enriched by the inclusion of patients with the condition... they provide the most valuable insights”- Theresa Mullin, Associate Director for Strategic Initiatives, CDER (3/19/18)

- **Involvement of all stakeholders**
- The FDA wants to include the patient perspective: help them to help you
- Have the right people in the room and ask the right questions: identify issues up-front that FDA should be addressing to maximize impact of meeting
- Encouraging to patient population that advocacy groups are collaborating with the agency
- Patients are able to express what matters most to them and take charge of their health
- Advocacy work is never done, follow up!

**BENEFITS OF ENGAGING
EARLY AND OFTEN:
ACCESS!**



**Future opportunities to express
to FDA what matters most to
patients**