

FDA Patient Representative ProgramSM



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Advisory Committee Oversight and Management Staff

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FDA Patient Representative Program

- Began in 1990s and evolved.
- Patients having an active role on FDA Advisory Committees and in consultations with review divisions.
- Patient voice represented in important discussions about regulatory decision-making.
- Furthers an understanding and appreciation for FDA's role in medical product development, review and patient protection.
- Presence at the table.



Experiences Represented

200 FDA Patient Representatives

300-500 diseases/conditions/device experiences

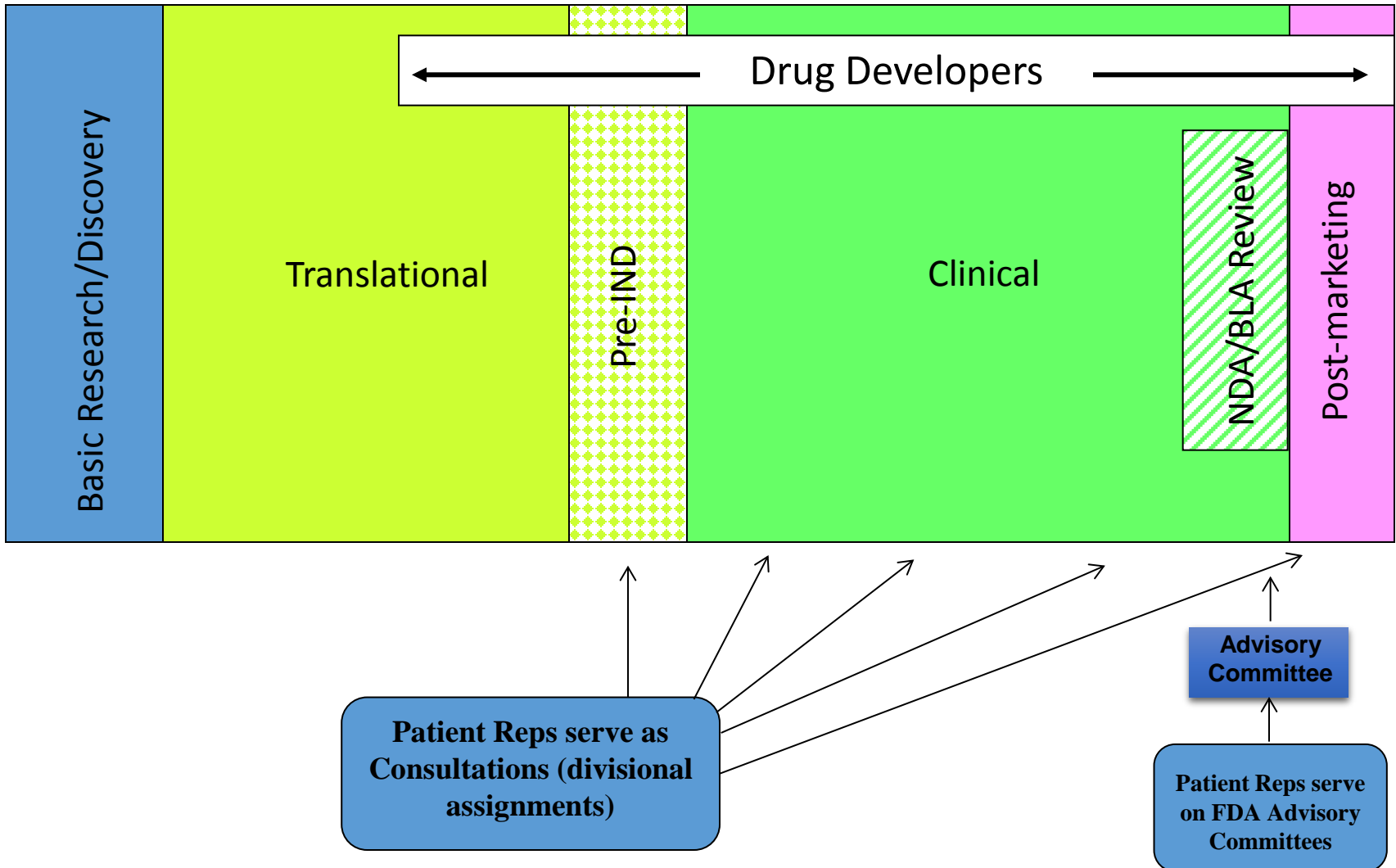
- AIDS/HIV
- Alzheimer's Disease
- Asthma
- Cancer (various)
- Cardiovascular disease
- Cerebral Palsy
- Crohn's disease
- Cystic Fibrosis
- Duchenne Muscular Dystrophy
- Diabetes
- Diabetes (insulin pumps)
- Fabry Disease
- Hepatitis B
- Hepatitis C
- Infantile Spasms
- Lung Transplantation
- Lupus
- Lysosomal Acid Lypase Deficiency
- Major Depressive Disorder
- Muscular Dystrophy
- Obesity/Weight Control
- Opioid Use
- Parkinson's Disease
- Pompe Disease
- Sickle Cell Disease
- Short Bowel Syndrome
- Temporomandibular joint disorder
- Transplantation

Becoming an FDA Patient Representative

- Personal experience with the disease or condition as either a patient or primary care giver.
- Patient community awareness: active in patient advocacy organizations, knowledgeable about treatment options and research, other advocacy activities.
- Someone who is analytical and objective, doesn't need to be a scientist but should grasp scientific principles and understand issues, experienced with decision making based upon complex information.
- Minimal or no conflict of interest.
- Good communications skills.
- Commitment to serve.



Where Patient Reps Intersect with Drug/Biologic Development?



FDA Patient Representatives on Advisory Committee Meeting Panels

- Temporary voting members.
- Screened for each assignment.
- Other disciplines at the table.
- Across all medical product Centers.
- 40-60 assignments/year.



FDA Patient Representatives also serve...

...as consultants with review divisions:

- Brings the voice earlier in the regulatory process.
- Divisional “homework” assignments.
- Consult directly with scientific review staff and sponsor
- Closed meeting (telecon).

...at workshops

...on symposiums





We Train and Prepare for Service!!!

- Describe significance of program
- Describe FDA regulatory framework and decision-making process (FDA 101)
- Share experiences: internal and peer
- Describe scenarios for the meeting
- Offer regular webinars (training modules)
- Provide online resources for patients
- Host Annual Patient Representative Workshop

FDA Patient Representative Program 2017 Training Workshop Cohort

