PATIENT FOCUSED DRUG DEVELOPMENT: THE TIME IS NOW

Marjorie Gatlin, MD
VP and Head, Regulatory Advertising & Promotion and
Risk Management
Novartis Pharmaceuticals Corporation
The opinions expressed in this presentation and on the following slides are solely those of the presenter and not necessarily those of Novartis Pharmaceuticals Corporation (“NPC”). NPC does not guarantee the accuracy or reliability of the information provided herein.
* Increased patient engagement leads to better patient outcomes, improved quality of care and reduced health care costs

* An important aspect of achieving better patient outcomes is the development and approval of treatments that address the unmet needs of patients in a benefit risk framework that reflects patients perspectives
What is “Patient Focused Drug Development?”

- ‘Patient Focused Drug Development’ lacks a consistent definition
- Is gaining momentum in the US due to a number of different factors
- Goes beyond Patient Reported Outcomes
What is “Patient Focused Drug Development?”

Bringing medicines to market to prevent, treat or cure illnesses in a process that is informed by direct patient/caregiver input throughout.
It All Begins With the Patient Journey

- Patient Access
- Benefit Risk
- Unmet Need
- Patient Journey
Meeting the Challenges of Direct Patient Engagement

* Is your company ready for direct patient engagement?
* Build cross-functional consensus on the urgency for direct patient engagement
* Are there processes and frameworks in place to engage patients throughout the lifecycle of a product?
* Ensure that you have alignment with your Patient Advocacy department.
* Create processes for setting up appropriate consulting agreements and contracts.
* How will insights be archived and shared across the organization?
What Are the Challenges in Reaching the Patient?

- Who is the ‘right’ patient?
- How do you ensure that you have heard all relevant patient perspectives?
- How do you reach the patients?
  - Patient Advocacy Groups
  - Clinical Trial Investigators
- Put processes in place to identify the right patient(s) for a particular engagement
- Leverage technology, e.g. social media, on-line communities to connect with patients
Meeting the Challenges of Direct Patient Engagement

* Patient engagement doesn’t end with product approval
* Patient perspective in ensuring access is key
* Patient perspective informs the definition of value
* Patient perspective informs disease management and adherence programs
Meeting the Challenges of Direct Patient Engagement

- Challenges still remain in translating the learnings from the patient journey to product development
- A clear path to incorporate endpoints that reflect the patient’s perspective of value is needed, beyond PROs
- A framework for appropriate communication of value information to patients, payers and prescribers is lacking
Thank you