“Inspired by Patients
Empowered by Me”

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MSD
An Industry Perspective

The need for an open infrastructure for proactive patient engagement throughout the life cycle of a product.
MSD Mission:
A consistent focus on patients

“We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear. How can we bring the best of medicine to each and every person? We cannot rest until the way has been found with our help to bring our finest achievements to everyone.”

- George W. Merck, 1950
Drug invention

--Pharma has longest, most expensive, most risk, most regulated interval from concept to product

R&D commitment in context

- Pharma companies spend $1.24 B USD and 10-15 years to develop a new biopharmaceutical (pre-approval costs 2007)

- Apple spent $150 M USD and 30 months to develop the iPhone.

Source: DiMasi and Grabowski, Managerial and Dec Econ 2007;28(4-5):469-479


Few organizations on the planet can do what pharmaceutical companies do: go from target identification to bringing innovative medicines and vaccines to patients globally…
Direct interactions with patients

For 100 years, MSD has relied on physicians to provide patient perspective.

Patients have access to more information.

Patients are now “payers”.

Patients are organized.

We aim to establish bi-directional interactions with patients leading to invention and innovation.
The MSD Framework*
“Patient Inspired Innovation”

The Opportunity

- Holistic understanding of patient life context/journey
- Value of Medicine perspective
- Real World Trial endpoint selection and assessment
- Benefit: Risk Assessment vs. Standard of Care
- Discovery (PK, metabolism, PH1)
- Pre-Clinical Development (PH2-PH4)
- Clinical trial design/protocol input/feasibility
- Clinical trial recruitment tools/website optimization
- Market image, delivery, dosage
- Packaging design

- Adherence Programs
- Adherence to principles & standards of Health literacy, Transparency & Privacy
- Return of Results
- Patent Expiration
- Post Licensure
- Patient assistance & access, patient support and compassionate use programs
- Ongoing Patient Organization input and feedback

- Return of Results
- Patient Medication Guide

*Based on Office of the CMO- Voice of the Business Feb- April 2014 (MRL, GHH, OCMO, MMD)
Representative Feedback from MSD leaders across all divisions

• "We need to learn from patients and understand their individual risk-benefit as they are all certainly not average."

• “We need to understand what is viable for patients, understand their challenges and their preferences”

• “We need to make better treatments…not just better drugs”

• “We need scientific tool validation development while we are engaging and learning—don’t wait for perfect”

2014; N= 150, Survey fielded by Office of the CMO Strategy Office
Agreement on the importance of incorporating the “voice of the patient” into the research continuum

BUT....

- Industry is motivated on elements of recruitment and retention and academia is focused on whether there is a funding/sponsor mandate

- Patient orgs are focused on early engagement

- Rare disease networks that involve patient groups who are phenotypically similar are establishing networks, and major stakeholders vested in solutions who are collaborating to bring about effective therapies

- Key differences exist in perceived barriers and benefits of partnering and engagement that have implications in shaping policy. This recognition could inform the development of best practices and is dependent on our collective ability to understand success factors; and get on course

“IT TURNS OUT THAT WHAT IS REALLY BOTHERING THE PATIENT AND WHAT IS REALLY BOTHERING THE DOCTOR CAN BE RADICALLY DIFFERENT THINGS.”

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research FDA
Our Call for Action

• Make **Sponsorship** in key internal functions heard

• Deliver Organization **structure change** with an **undisrupted focus** on the patient

• Incite a foundational cross company **culture change** with employees

• Implement **patient engagement programming** that starts to inform internal decision making **throughout medicines development**

• High engagement with **Stakeholders** and Leadership with **Public-Private Initiatives** Globally
“When you begin to look at a trial from the patient’s perspective and consider the complexity of the trial and what we are asking them to do, is it any wonder that so many patients are refusing to participate? And is it any wonder why so many patients choose to withdraw from a clinical trial?”

Mark Travers, Global Head of Monitoring Excellence and Interim Head of North America Clinical Operations, MSD.
MSD Team: GC-SMPP

- A small, diverse group of well-networked physicians
- Deployed globally to support the CMO and patient needs
- Broadly experienced with high empathy and respect for patients
- subspecialty expertise covering areas of high priority to MSD

Richard Murray
Deputy CMO

Evalyn Grant
Respiratory & Drug safety
Michael Harbour
Infectious Diseases
Susan Manoff
Vaccines
Luther Clarke
Cardiovascular
Yun-Ping Zhou
Diabetes & Endocrinology
Paul Robinson
Europe
Elaine Perry
Drug Safety
Michelle Vichnin
Oncology

Structure/ Undisrupted
We are dedicated to “Protection” (of patients rights)
Listening to Patients

Types:

• Patient Dialogues
• Patient Input Forums
• Patient Leader Advisory Boards
• Patient Leader Guest Lecturer
• Social media
• Big data
• Unaffiliated communities (PatientsLikeMe, Wego Health, Patient Power, Smart Patients)
The average patient is based on many, but is no single individual.
Partnering With Patients in the Development and Lifecycle of Medicines: A Call for Action

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Abstract
The purpose of medicines is to improve patients’ lives. Stakeholders involved in the development and lifecycle management of medicines agree that more effective patient involvement is needed to ensure that patient needs and priorities are identified and met.
The patient's voice in the evaluation of medicines

“This will involve challenges to all the stakeholders”

• “commit to best practices and learn”

• “take account of the way values vary between patients and change over time”

• “identify where qualitative and quantitative input is needed and validate new tools”

• “look at what training and support is needed to maximize patient involvement”

Thank ye!