“Medical Affairs: Introduction & Overview”

Graduate School Workshop  
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Workshop Outline

- **Medical Affairs (MA): An Overview**
- **World Café Exercise—Immediate Review of MA**
- **Case Simulation--Product Launch**
- **Group Presentations**
Context

For the First time in history:

• **Six generations living together** in the world

• **Four generations together** in the workplace (to mirror Academia)!
Medical Affairs: Internal Partners

- Advocacy & Policy
- Regulatory Affairs
- Research & Development
- Drug Safety
- Sales & Account Management
- Compliance & Legal
- Marketing & Business Development

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Corporate Communications
Manufacturing
Senior Administration: Human Resources & Finance
Medical Affairs: Functions

- Medical Affairs: Chief Medical Officer
  - Medical Director (Global)
  - Medical Director (Domestic)
  - Scientific Communications
  - Post-marketing Clinical Research
  - Health Economics & Outcomes Research
  - Innovation & Digital Health
  - Scientific Education (CE & CME)
  - Knowledge Specialists
  - Medical/Scientific Liaisons
Medical Affairs Personnel & Credentials

- *Predominantly* with Scientific Backgrounds

- Increasingly with Business, Public Health, & Health Policy Backgrounds and Experience

- Masters Degrees

- Doctoral Degrees (**PhD**, **PharmD**, **MD**)

- New Board Certification in Medical Affairs
World Café Exercise

Sharing perspectives & understanding of the roles of Medical Affairs
Medical Affairs Defined

A *dynamic and rapidly growing* area of the Pharmaceutical and Device Industries that focuses on *research, knowledge, and education* and provides *primary scientific and medical support* for a company’s marketed products and development pipeline.
Digital Health ("EMT")

- **eHealth**
  - *Electronic Records (EHRs/EMRs)*
  - *Patient Portals*
  - *Research applications/eCROs*

- **mHealth**
  - *Apps*
  - *Sensors*
  - *Wearables*
  - *Point of Care Devices*

- **tHealth**
  - *Telehealth (Project ECHO)*
  - *VA*
  - *UPMC (Anywhere Care)*
reSET© App

- *First FDA approved clinical app* (August 2017)
- Used in Addiction Medicine
- A tool that augments medications and therapy to extend patient sobriety
- Launched by Pear Therapeutics
“The Digital Pill”

- FDA Approved on 11/13/17

- *First drug in the U.S. with a digital ingestion tracking system*

- Abilify MyCite (*aripiprazole* tablets with sensor) has an ingestible sensor embedded in the pill that records that the medication was taken

- Indicated for the treatment of:
  - Schizophrenia
  - Acute treatment of manic & mixed episodes associated with bipolar I disorder
  - Add-on treatment for depression in adults
“The Digital Pill”—How It Works

- Sends a message from the pill’s sensor to a wearable patch
- The patch transmits the information to a mobile application
- This App allows patient tracking of medication’s ingestion on their smartphone
- Patients can also permit their caregivers & physician(s) to access the information through a web-based portal
SOCIAL MEDIA & MEDICINE
Trends

• **Snapchat** will be the newest customer communication channel of interest and growth for Pharma

• For *Truvada* marketing, Gilead uses Snapchat, Tumblr, & dating sites

• **Twitter** and **LinkedIn** are being utilized most frequently at major congresses for immediate dissemination of landmark data and press conferences

• **Mobile** is the most rapidly growing digital platform (*but print is still valuable!*
Trends (cont’d)

Technology & Social Media will be utilized more prominently for solutions (health equity & translator services):

- 5G
- Augmented Reality & Virtual Reality
- Artificial Intelligence/Deep Learning & Artificial Neural Networks
- Video
- Audio enabled
- Internet of Things
- Point of Care
- WiGig
- Tileable Screens
- Blockchain
"May there never develop in me the notion that my education is complete but give me the strength and leisure and zeal continually to enlarge my knowledge."

- Maimonides -
One Health Initiative

http://www.onehealthinitiative.com/about.php
One Health Definition

• Worldwide strategy for expanding interdisciplinary collaborations & communications in all aspects of health care for:
  – *Humans*
  – *Animals*
  – *The environment*

• The synergism achieved will advance health care for the 21st century and beyond

• With proper implementation, it will help protect and save untold millions of lives in our present and future generations
Planetary Health

The Economist

SPECIAL EDITION
PLANETARY HEALTH
From The Economist 2014

In this issue:
- Climate change and poverty
- The future of the oceans
- The melting north
- Livestock diseases
- China and the environment
Planetary Health Initiative

• A new multi-disciplinary global effort

• Aims to identify solutions to health risks posed by our poor stewardship of our planet

• Seeks to influence both international & national approaches to health through:
  – Advocacy
  – Partnership
  – Awareness raising

• Plans to create *policy change* that better balances human advancement with environmental & biodiversity sustainability