

RUTGERS

Robert Wood Johnson
Medical School

“Medical Affairs: Introduction & Overview”

Graduate School Workshop

Center for Advanced Biotechnology & Medicine

Newark, New Jersey

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Workshop Outline

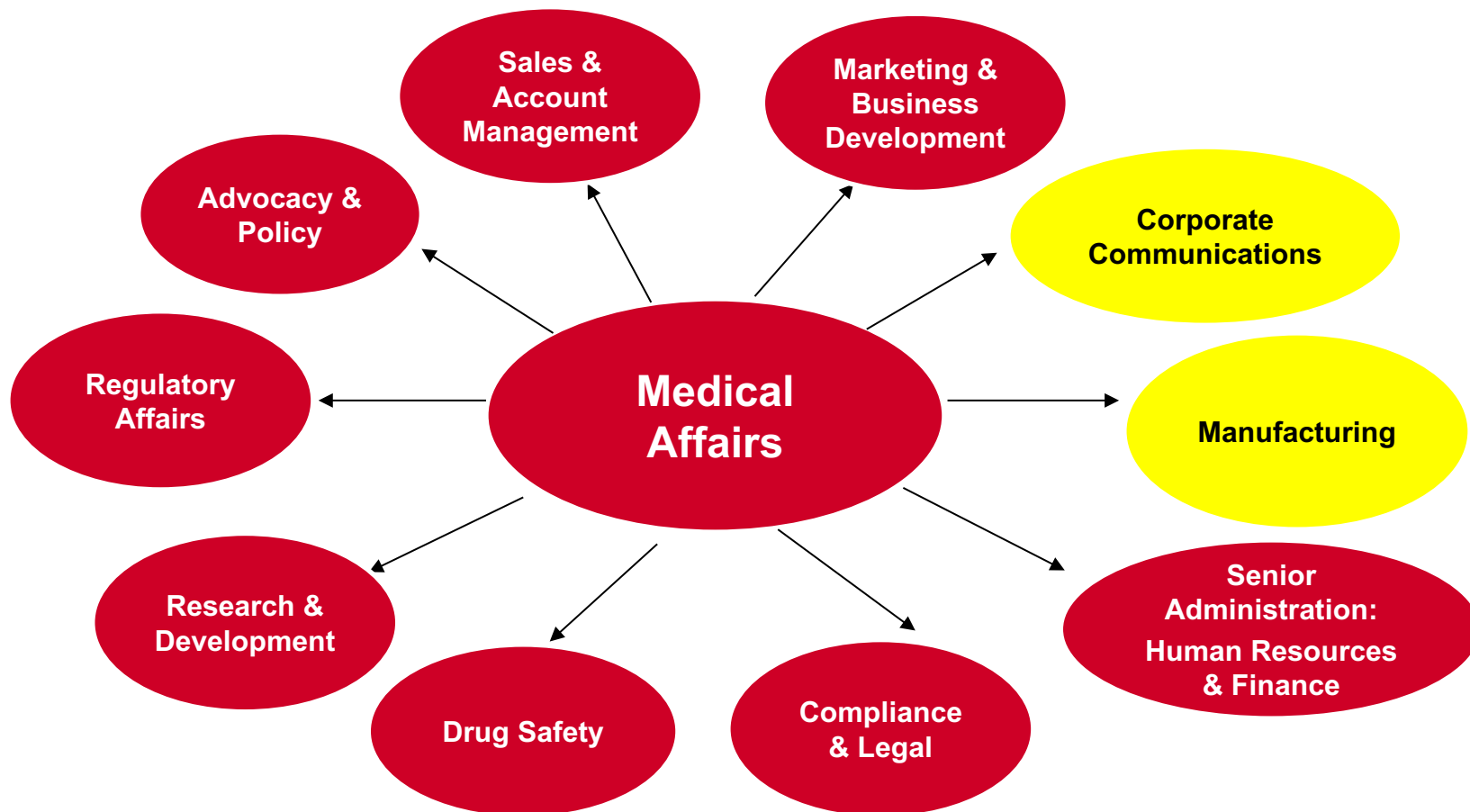
- *Medical Affairs (MA): An Overview*
- *World Café Exercise—Immediate Review of MA*
- *Case Simulation--Product Launch*
- *Group Presentations*

Context

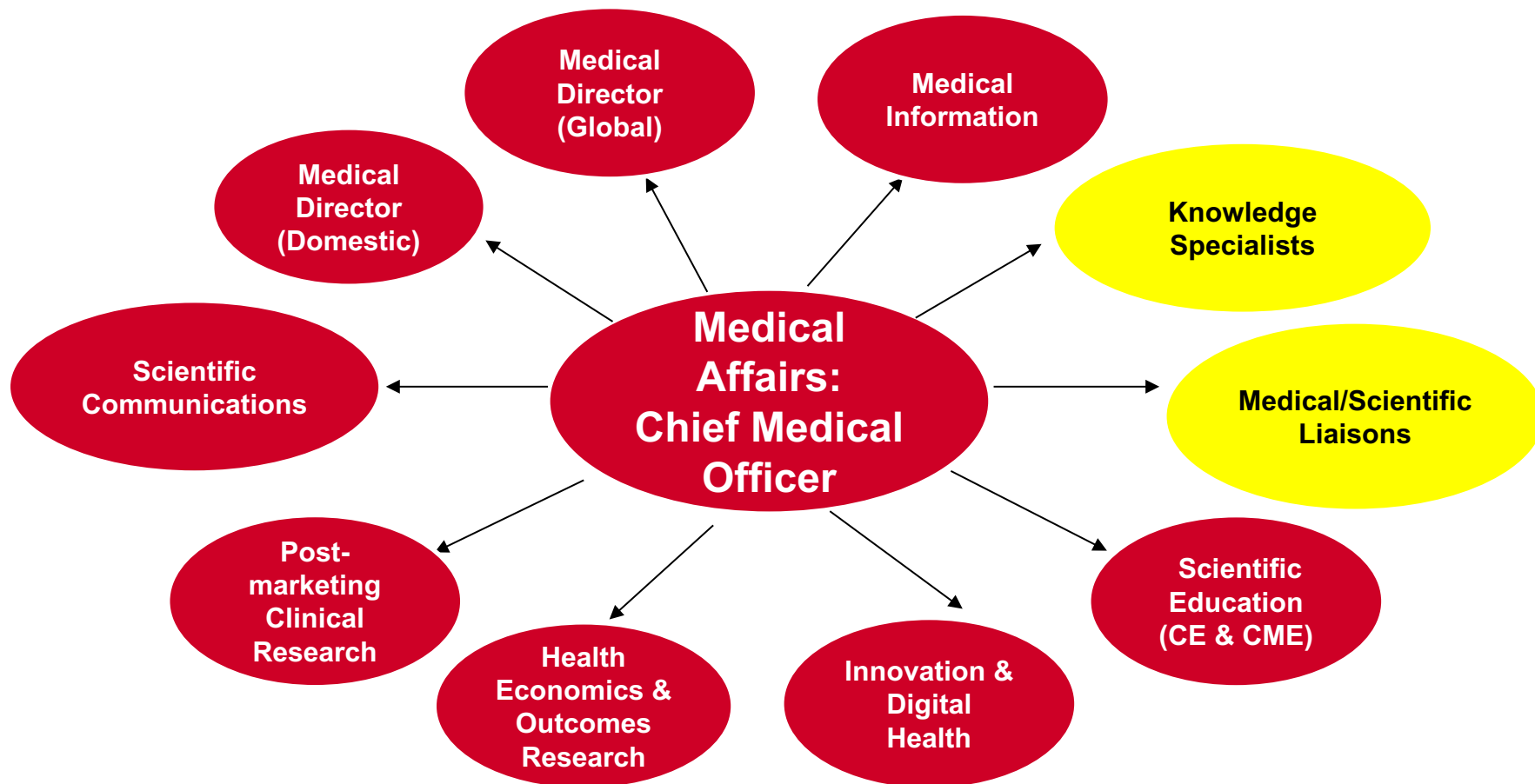
For the First time in history:

- *Six* generations living together in the world
- *Four* generations together in the workplace (to mirror Academia)!

Medical Affairs: Internal Partners



Medical Affairs: Functions



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 **smart phone**
- 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



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



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