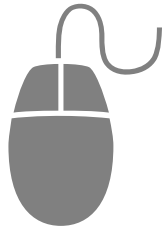
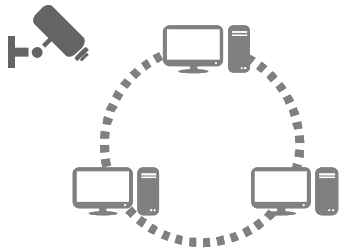


Mini Summit 13

The Challenges of New Channels: Digital Communications, Social Media, and Other New Technologies

International Pharmaceutical and Medical Device Compliance Congress
16th of May 2017, Lisbon, Portugal



Panellists

- ▶ **Grant Castle, Covington & Burling**
- ▶ **Giota Papamarkou, Ipsen**
- ▶ **Jessica Pfennig, AstraZeneca**
- ▶ **Melda Tanyeri, EY (Moderator)**

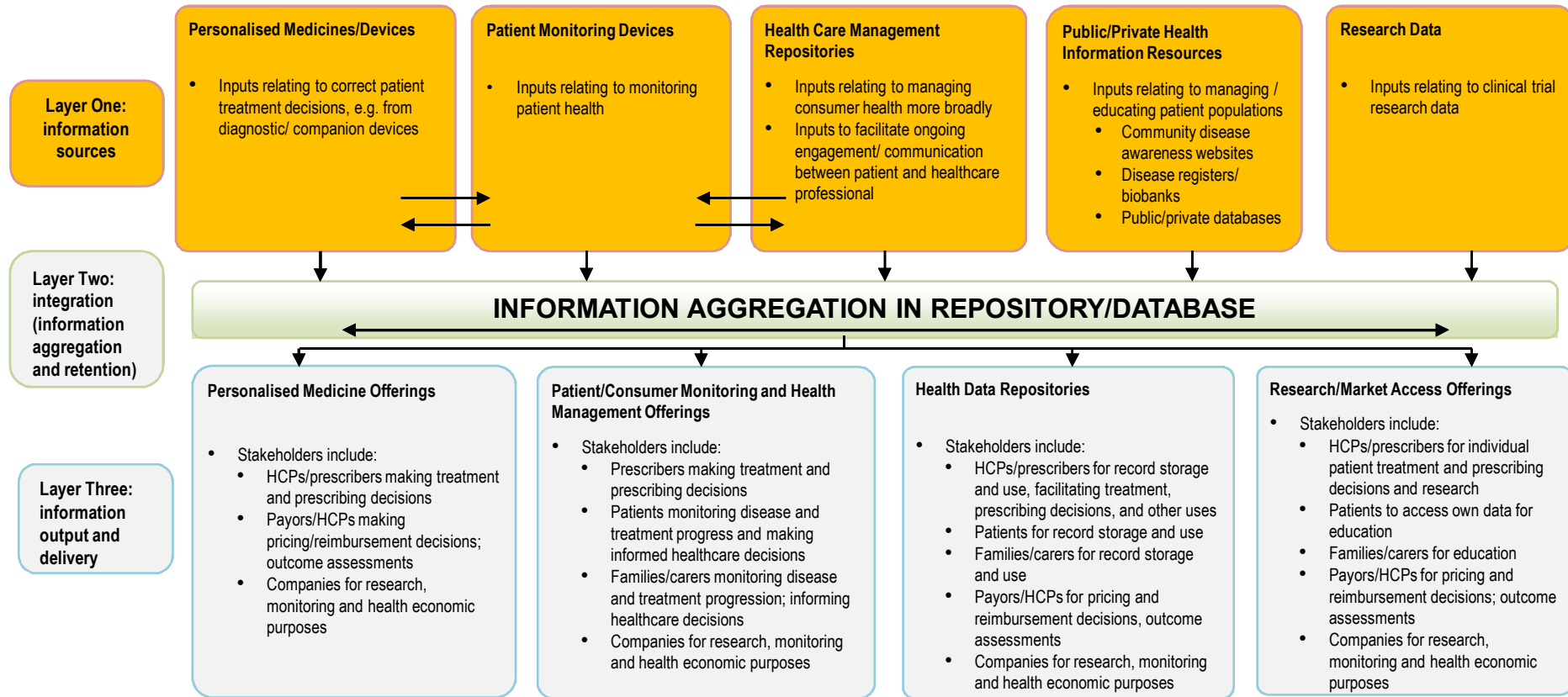
What is digital?



Digital activities: activities based on Internet or other platforms and technologies such as websites, applications, webconferences, eInteractions

Social Media: Web-based and mobile-based technologies which are used to turn communication into interactive dialogue between organizations, communities and individuals such as Facebook, Twitter, LinkedIn, YouTube, Viadeo, Instagram, Yammer and WeChat

Digital health: inputs and outputs



Digital Activities and Social Media

Benefits

Provide direct access to information (product related, disease related, other information relevant to the audience)

Help to overcome/address time and availability issues (live and on-demand activities)

Broader audience reach (corporate related information and initiatives through Social Media)

Reduce the costs associated with activities (webcasts/eInteractions vs. face-to-face activities)

No hospitality costs required for HCPs or other audience

Global Digital Activities

Key Challenges

Difference in approvals

- Differences on approved product information or status of approval among countries
 - Available information in Internet not valid for all countries or not appropriate for all audiences (e.g., product related websites)
 - Risk for activities being considered as attempt for off-label promotion in the pre-launch phase

Data privacy

Data privacy requirements when personal or individualised data may be collected (e.g., name, professional information, areas of interest etc.)

Difference in rules

- Rules/Requirements on content vary among countries
 - Disease awareness websites: risk for being viewed as disguised promotion
 - Disease awareness websites and fair-balanced treatments information

Access

- Need to ensure access to content by authorised/intended audience
 - Some countries do not require restricted access to product related websites
 - Authentication mechanisms needed including for einteractions and webconferences/webcasts

Social Media

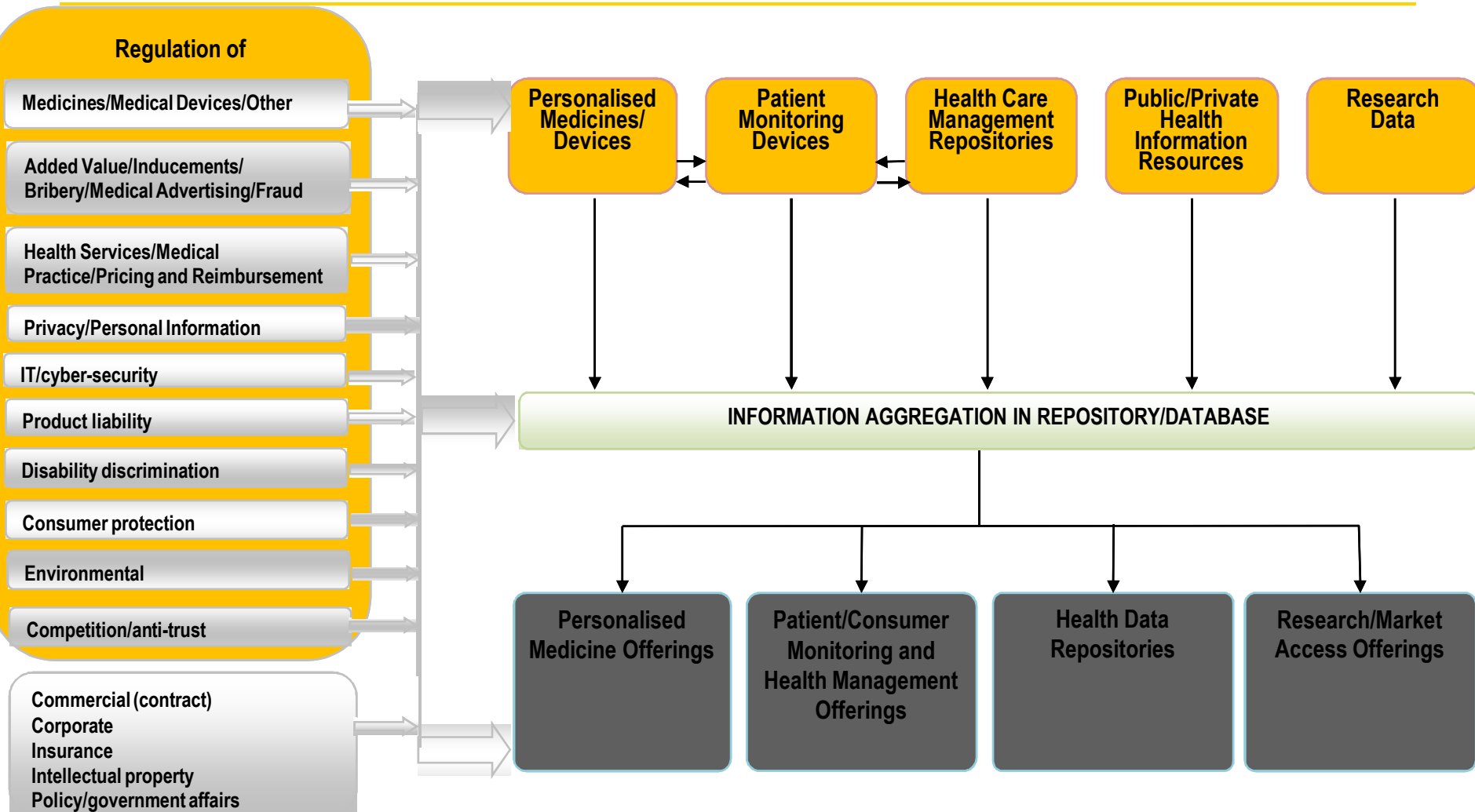
Key Challenges



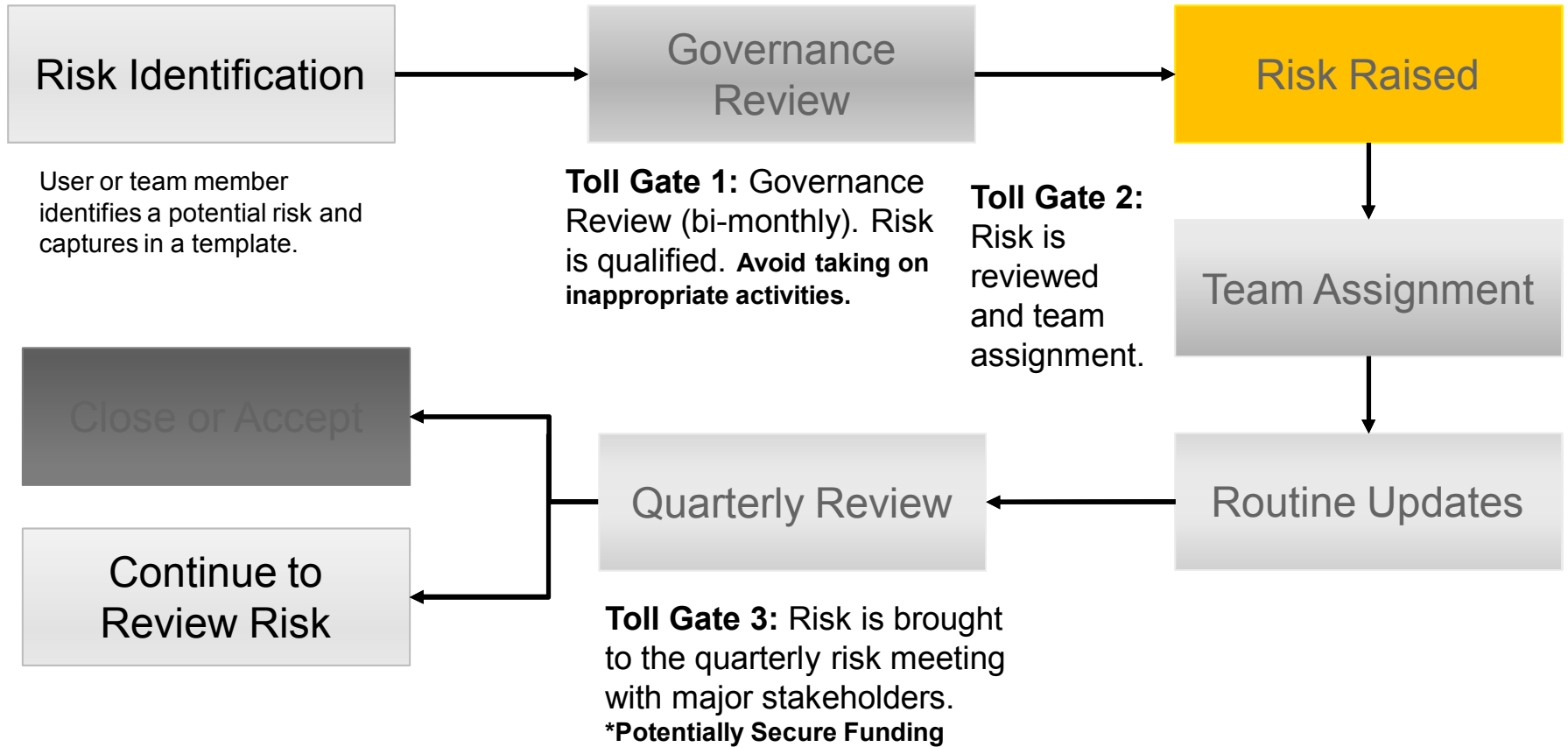
- Functionalities allow for information sharing quickly and easily (share, post, like etc.)
- Individuals' re-sharing of factual information shared already by a company (e.g., approval of new medicines/ indications) may be considered as promotion to general public
- Confidential or sensitive/ non publicly disclosed information can be quickly exposed; impact on company's image or infringement of laws/regulations
- Social Media listening and monitoring: adverse events data collection and reporting

Digital Health

Legal and regulatory landscape



Risk Management Process



Digital Risk Management

Digital Governance Scope

- ✓ Website - External Monitoring and Surveillance
- ✓ Mobile Apps – Tagging and Analytics
- ✓ Change in legislation/Change in requirements

Brand Protection:

- ✓ Social Media Accounts
- ✓ Domains and Rouge/Counterfeit Products
- ✓ Digital Reputation Damage
- ✓ Internal Auditing (IAS)
- ✓ Product Labelling & Content
- ✓ Vendor/Supplier Management Risks
- ✓ Data Protection/Privacy
- ✓ Training and policies

Exclusions
Security risks
Infrastructure risks
IT Group risks