Advanced Product Development & FDA Regulatory Considerations for Vendors

UNCLASSIFIED

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Purpose

To enhance understanding of medical product Advanced Development (AD) and related Food and Drug Administration (FDA) Regulatory Affairs considerations

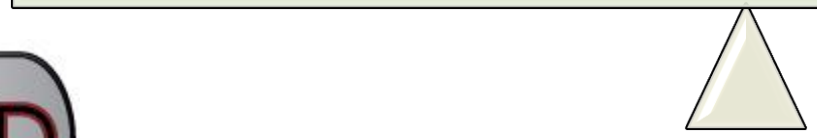
- AD Overview
- Planning for Product Transition
- AD Governing Processes
- Commercial Solutions
- How to Access and Work with AD
- FDA Regulatory Considerations

Panel Members

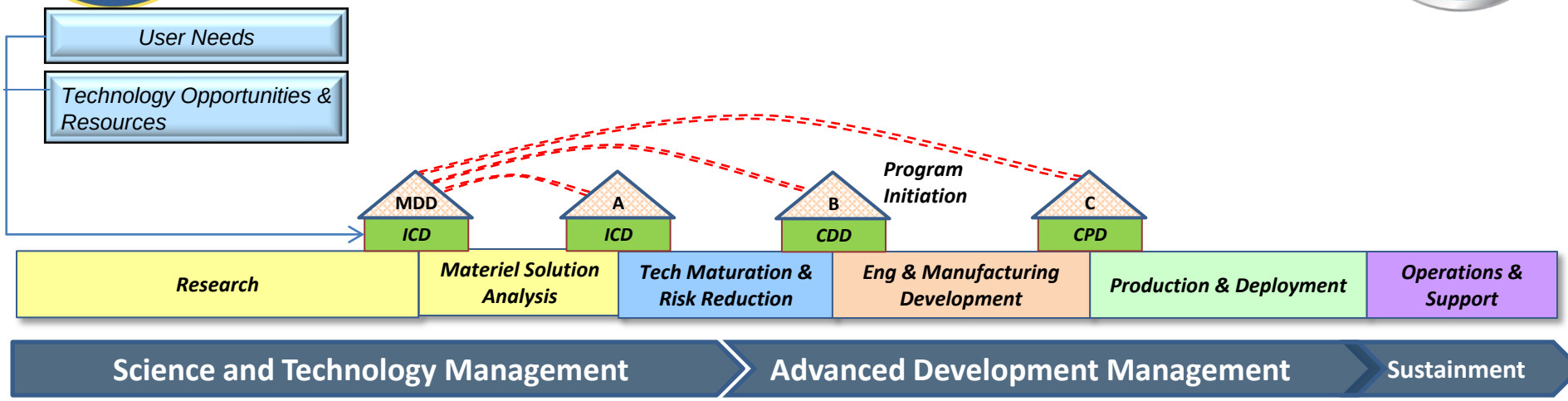
- Ms. Kathleen Berst - Deputy for Acquisition, US Army Medical Materiel Development Activity (USAMMDA), USAMRMC
- Dr. Tyler Bennett - Deputy for Acquisition, US Army Medical Materiel Agency, USAMRMC
- Dr. Carolyn Laurencot - Senior Regulatory Affairs Advisor & Acting Director Clinical Services Support Division, USAMMDA, USAMRMC
- CDR Joseph Cohn - Director, Advanced Development, Defense Health Agency Research, Development & Acquisition Directorate

From Science to AD

Requirements Pull	Technology Push
Office of Management and Budget Science & Technology Priorities	Knowledge Product Recommendations
Defense Health Program Science & Technology Priorities	Near-term Emerging Technologies
Army 2025 & Beyond	Future Technology Revolutions
Capability Needs Assessment	New Ideas from Labs



DoD's Medical RDTE Enterprise



Science and Technology Management | **Advanced Development Management** | **Sustainment**

Managed by Services or DHA Joint Program Committees	Managed by Service Project Managers or DHA AD Program Manager
• *Focus is on best research aligned to military gaps* •*Intramural laboratories* •*Extramural partners – industry, academia, other Government Agencies*	• *Focus is on testing and manufacturing safe, effective, affordable, and sustainable solution to meet military requirement* •*Extramural partners – industry, academia, other Government Agencies* •*Intramural laboratories*

Overview: The 5 "Ws"

Why?

To fill validated DoD gaps that provide solutions in saving Warfighter's lives

What?

Partnerships w/ industry, academia, & other gov't agencies to develop & deliver affordable, effective and timely solutions

When?

Early in the development process; after proof of concept studies, before & during preclinical and clinical trials

Who?

Certified Acquisition professionals w/ extensive project management & medical product development experience

Where?

Service specific

Army AD is located at Fort Detrick, MD & partners with industry & clinical sites worldwide

AD Translates Research Into Products

Translating Research Into Fielded Products

RESEARCH → ADVANCED DEVELOPMENT → FIELDED PRODUCT

Core Competencies
AD and Regulatory

- Advanced Medical Product Development
- FDA Regulatory Management
- Clinical Development
- Force Health Protection

DoD 5000

Materiel Solution Analysis → *Technology Maturation and Risk Reduction* → *Engineering and Manufacturing Development* → *Deployment* → *Operations and Sustainment*

Bridging the Valley of Death

Regulatory considerations start while the product is still in the tech base, before it enters AD

Fielded Products = Medically Ready Force

Product Lifecycle Focus

- What constitutes a “fielded” product?
  - Approved or cleared by the FDA for intended use
  - Environmentally suited
  - Acceptable to the user community
  - Translatable into clinical practice
  - Reimbursable

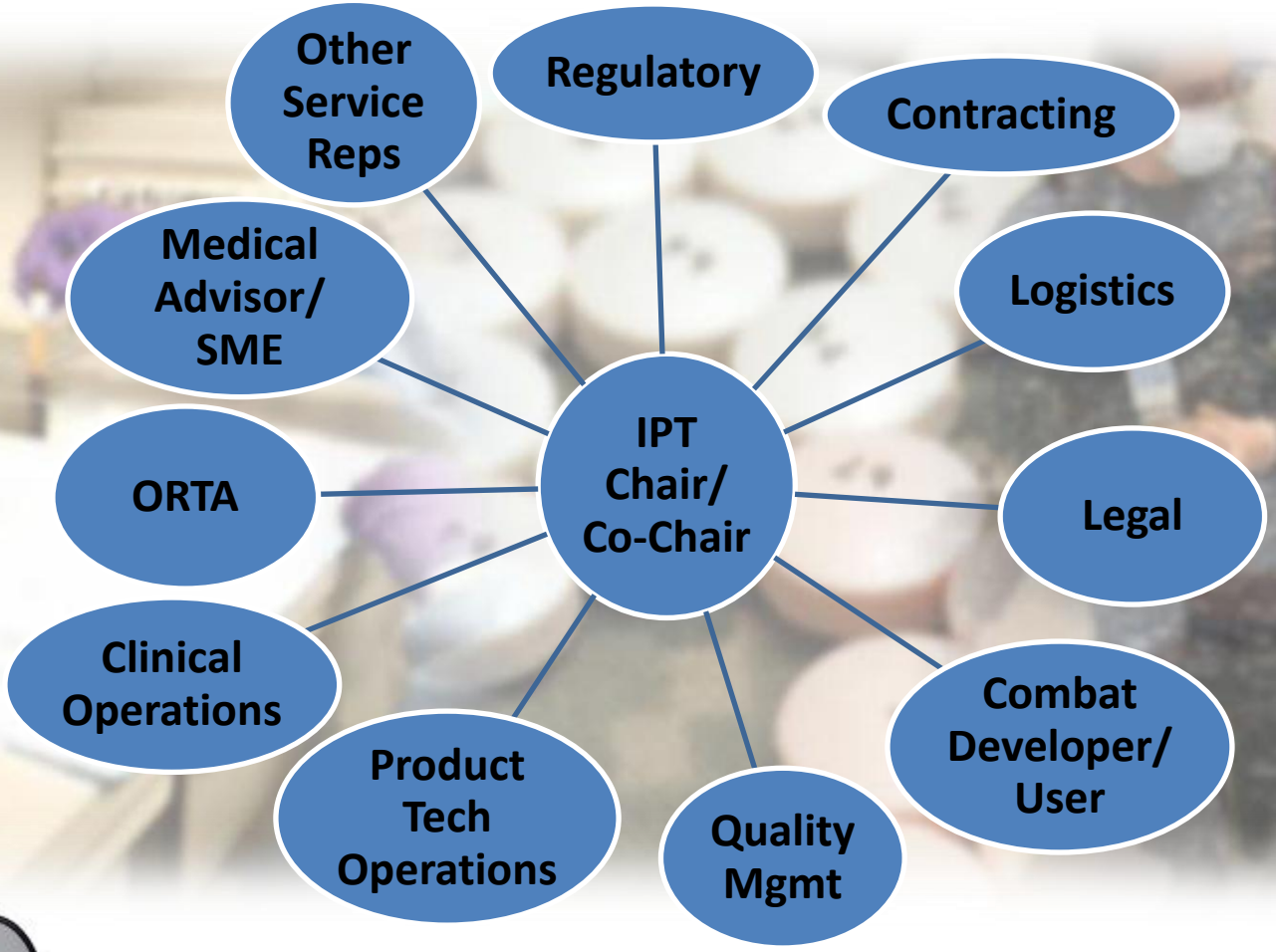
AD Translates Research Into Products

OUTCOMES FOCUSED!

Integrated Product Teams

IPTs are critical to AD success

Broad expertise is needed to develop and field products

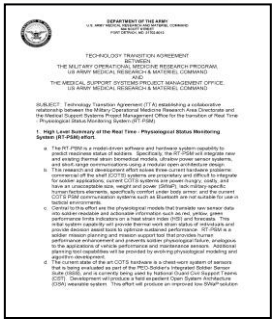


AD Translates Research Into Products

Planning Successful Transitions

- Begin with the end in mind
  - Know the requirement
  - “Good enough” now is better than perfect later
  - Avoid losing focus on what is really important
  - Keep focused → Avoid the allure of “bright, shiny objects”

- Integrate early → Many disciplines are on the critical path to product fielding
- Engage the FDA → Reviewers see more potential products in a month than most scientists do in a career
- Document transition agreements → ensures critical thinking & commitments when putting pen to paper



AD Translates Research Into Products

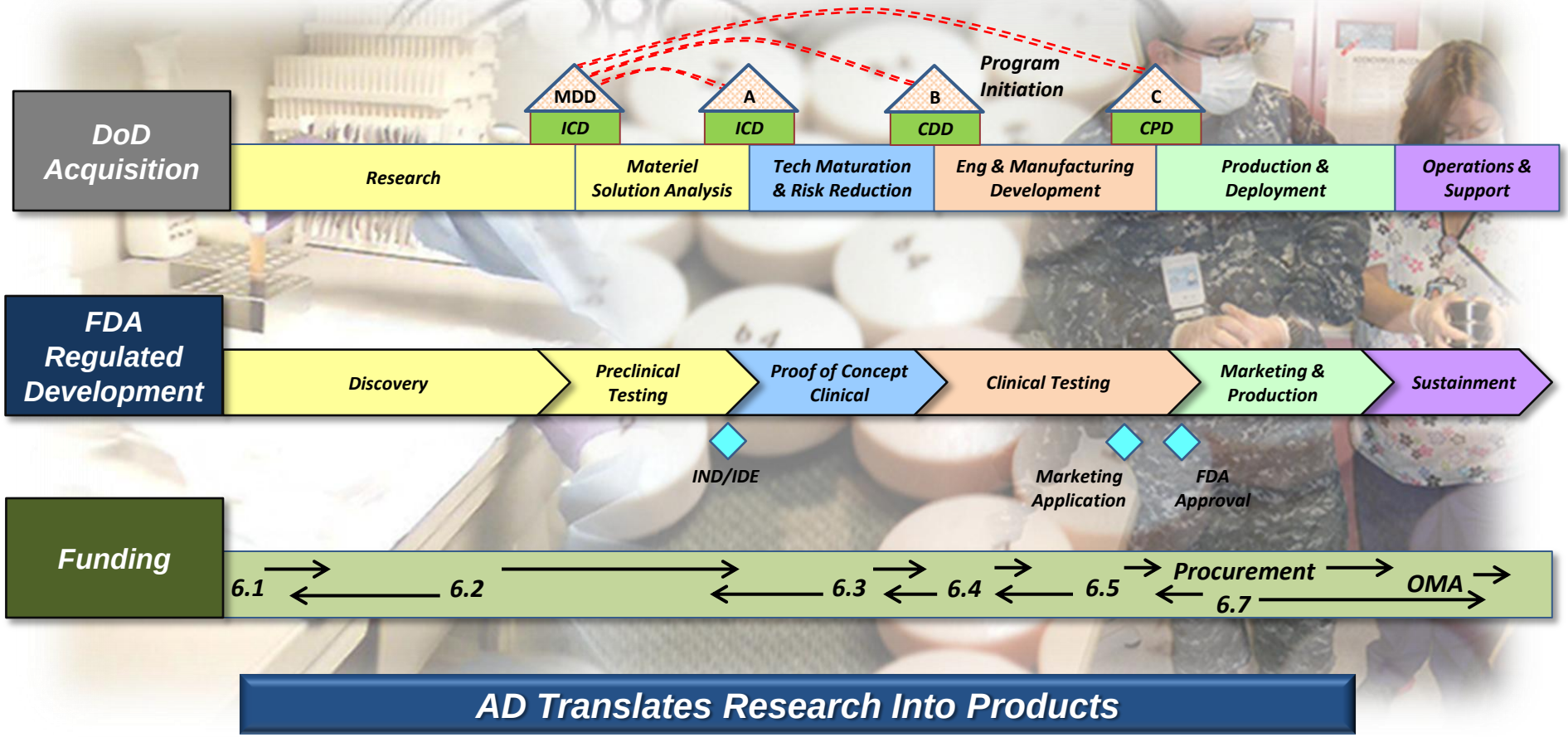
Product Development Issues

- Is there a DoD need (aka requirement)?
- What are the product candidates/alternatives?
- What is the viability of the industry partner?
- What are the projected and sunk costs?
- What has been the product's technical performance and schedule to date?
- What is the projected development schedule?
- Are there quality considerations?
- What is the sustainability of product in the marketplace?
- Is there an established manufacturing capability?
- What are the risks?
- What is the regulatory strategy for FDA regulated products?

AD Translates Research Into Products

Governing Processes

Integration of DoD 5000 and FDA Regulation Process



AD Translates Research Into Products

Commercial Solutions

- Why commercial solutions?
  - Development complete, reducing cost to DoD
  - Modifications (e.g. packaging, storage, etc) and operational testing (e.g., air worthiness) may be needed to employ for military use
- Examples include:
  - Vital Signs Monitors
  - Tourniquets
  - Oxygen Generators
  - Computed Tomography Scanners
  - Lab and X-Ray Equipment
  - C-Arms

- Issues
  - User Acceptance and Air Worthiness Testing
  - Information Technology - Authority to Operate and Risk Management Framework

AD Translates Research Into Products

Near-Term Products Needing Industry Support

- Products Under Development (3-5 years)
  - Post Traumatic Stress Disorder Treatment
  - Traumatic Brain Injury (TBI) Diagnostic
  - TBI Pharmaceutical Treatment
  - Soldier Readiness Monitoring: Non-invasive, near real-time physiological monitoring
    - Soldier worn and open architecture to improve actionable information
      - Currently based on the physiological strain index (heart rate based)
      - Additions to a comprehensive Soldier Readiness Score
        - » Cognitive Load, Alertness/Fatigue, Musculoskeletal Load, Electrolytes, Metabolism, Chemical and Biological Exposure
- Fielded Products Requiring Modernization (3-5 years)
  - Deployable CT scanner
  - C-arm X-ray apparatus
  - Military oxygen generating system
  - Pneumatic tourniquet

How to Access and Work with AD

- Access
  - New Products & Ideas Website (http://mrmc-npi.amedd.army.mil/)
  - Sponsored Meetings (e.g., USAMRMC Vendor Day, MMPD, Military Health System Research Symposium)
  - Response to Fed Biz Ops released requests

- Working with AD:
  - Cooperative Research & Development Agreements (CRADAs)
  - Materiel Transfer Agreements
  - Contracts - Full & Open Competition
    - Medical Product Research & Development: Indefinite Delivery, Indefinite Quantity
    - Small Business Innovative Research/Small Business Technology Transfer grants

AD Translates Research Into Products

FDA Regulatory Considerations

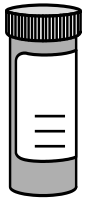
- FDA's regulatory decisions are data driven & based on a benefit-risk assessment
  - Unique for the disease, patient population, & agent(s) being evaluated
  - Informed by science, medicine, policy, & judgment
- FDA makes regulatory decisions are bounded by applicable law, regulations & policy (i.e., Food, Drug, and Cosmetic Act)
- The goal is FDA licensure/clearance
  - Understand information needed for package insert/product label **prior** to initiating clinical studies
- Develop a regulatory strategy to mitigate risk & employ quality systems in all aspects of product development
- Engage with the FDA early & often
- Establish an experienced product development team & communicate with all members of the team regularly

The Scheme of Things

FDA

Good Manufacturing Practices (GMPs)

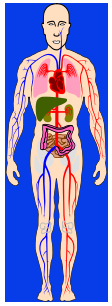
Regulations for manufacturers of Foods, Drugs, Cosmetics to assure the purity, quality and consistency of their product (Quality Systems for devices)



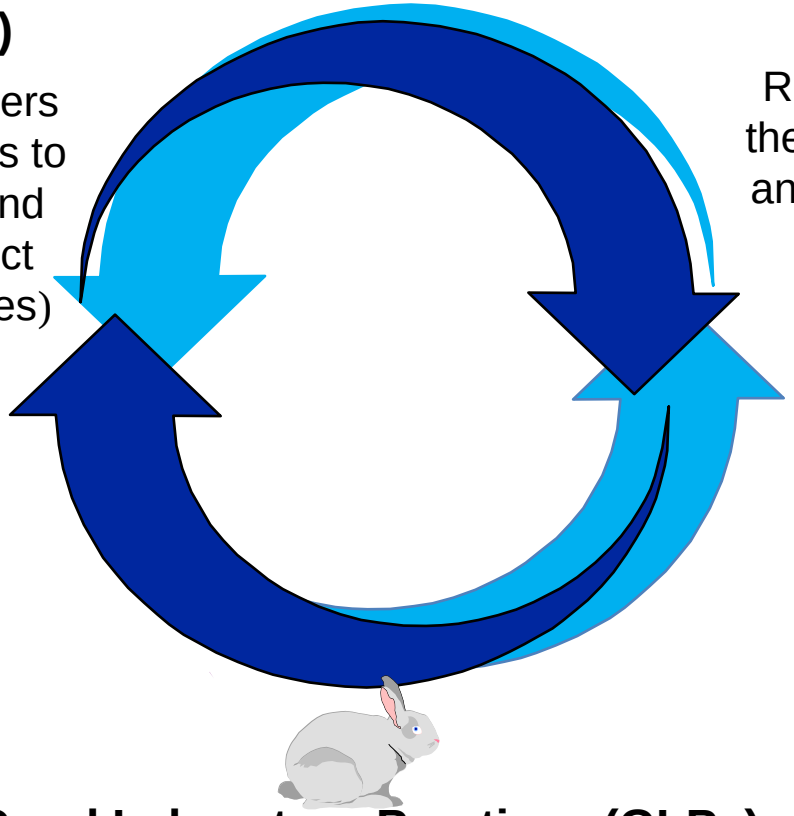
Manufacturer

Good Clinical Practices (GCPs)

Regulations to help assure the scientific quality, integrity and ethics of clinical studies conducted on humans



Investigator



Good Laboratory Practices (GLPs)

Regulations to help assure the scientific quality and integrity of data from non-clinical (animal) laboratory studies

From: Dr. Pilaro, CBER, FDA

Quality Data

- Product development generates evidence to support product licensure **and** commercialization

- Evidence generation should begin with the initial clinical trial
  - Relative efficacy needs to be evaluated pre-market
  - A ‘living’ process updated throughout the product lifecycle to reflect new internal data in addition to the latest external demands

- Medical product manufacturers need to satisfy the sometimes divergent needs of both licensing authorities and payers

- Time to market does not mean time to FDA licensing but time to reimbursement

Questions?

Ready and Deployable Force	Combat Casualty Care	Rehabilitate and Restore

Advanced Developers and Regulatory support teams deliver quality medical solutions to protect, treat, and sustain the health of Our Service Members

For additional questions after the conclusion of the conference, send an email message to usarmy.detrick.medcom-usamrmc.mbx.mmpd@mail.mil