

Vaccine Process Development: *Challenges and Opportunities from Project Management Perspective*

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Learning Objectives

After the presentation, the attendees should be able to:

1. Identify the overview and challenges of drug / vaccine development process.
2. Gain an understanding of the different complexities involved in the drug / vaccine development process.
3. Enumerate the diverse challenges and opportunities in vaccine development and manufacture.
4. Identify the role of Project Management in minimizing the enormous challenges in drug / vaccine expediting licensure.
5. *Beyond the Pandemic: Understand Project Management strategies for the next chapter of innovation in vaccine development.*

Presentation Outline

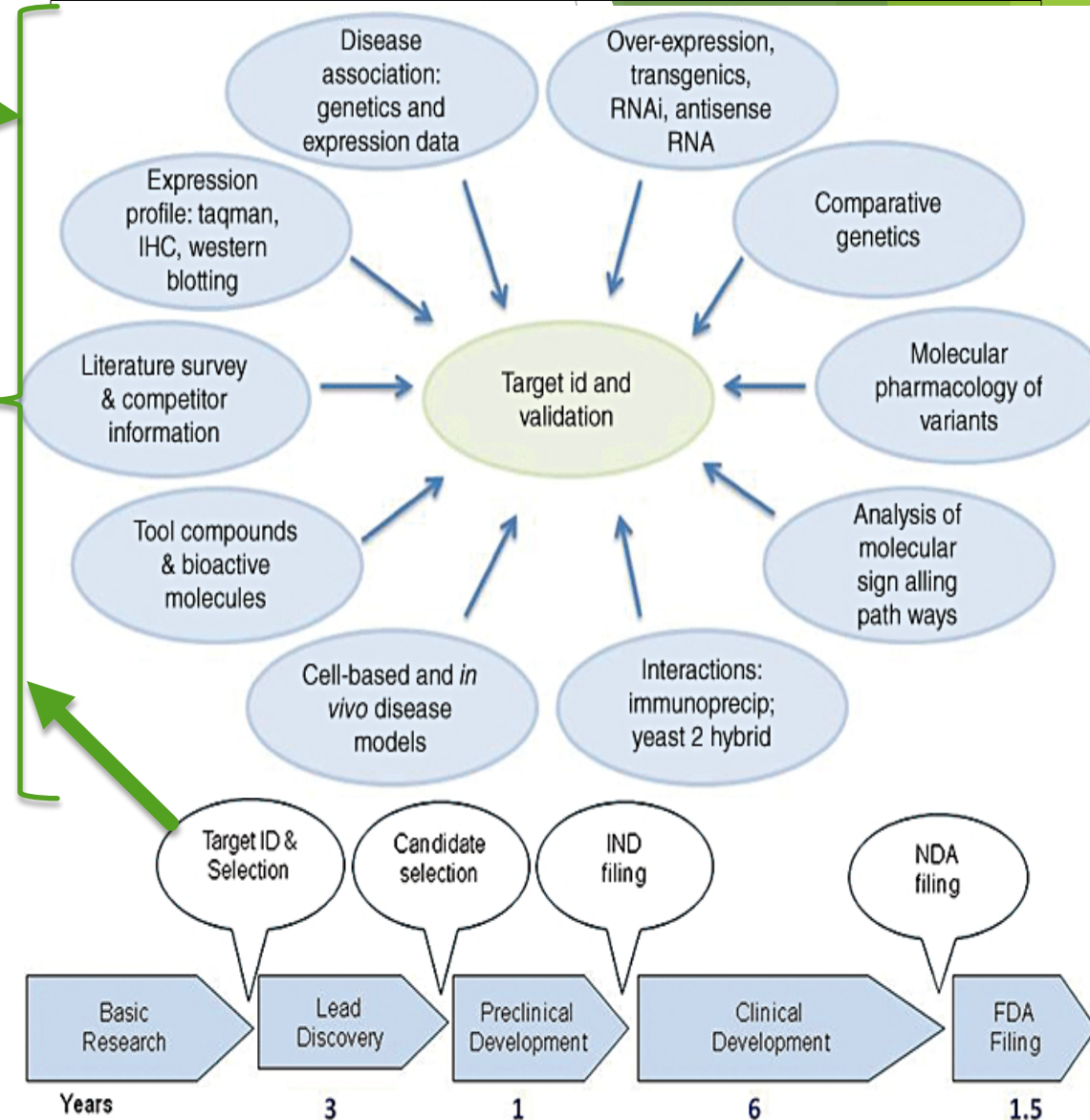
- Overview of Drug / Vaccine Development Process
- Overview of Challenges in Drug & Vaccine Development Process
 - Complexities
- Opportunities for Successful Drug & Vaccine Development
- Project Management Perspectives
 - Application of PjM Tools (Advanced)
 - Next chapter of Innovation in Vaccine Development – AI, EI & New Technologies
- Conclusion – Key Takeaways

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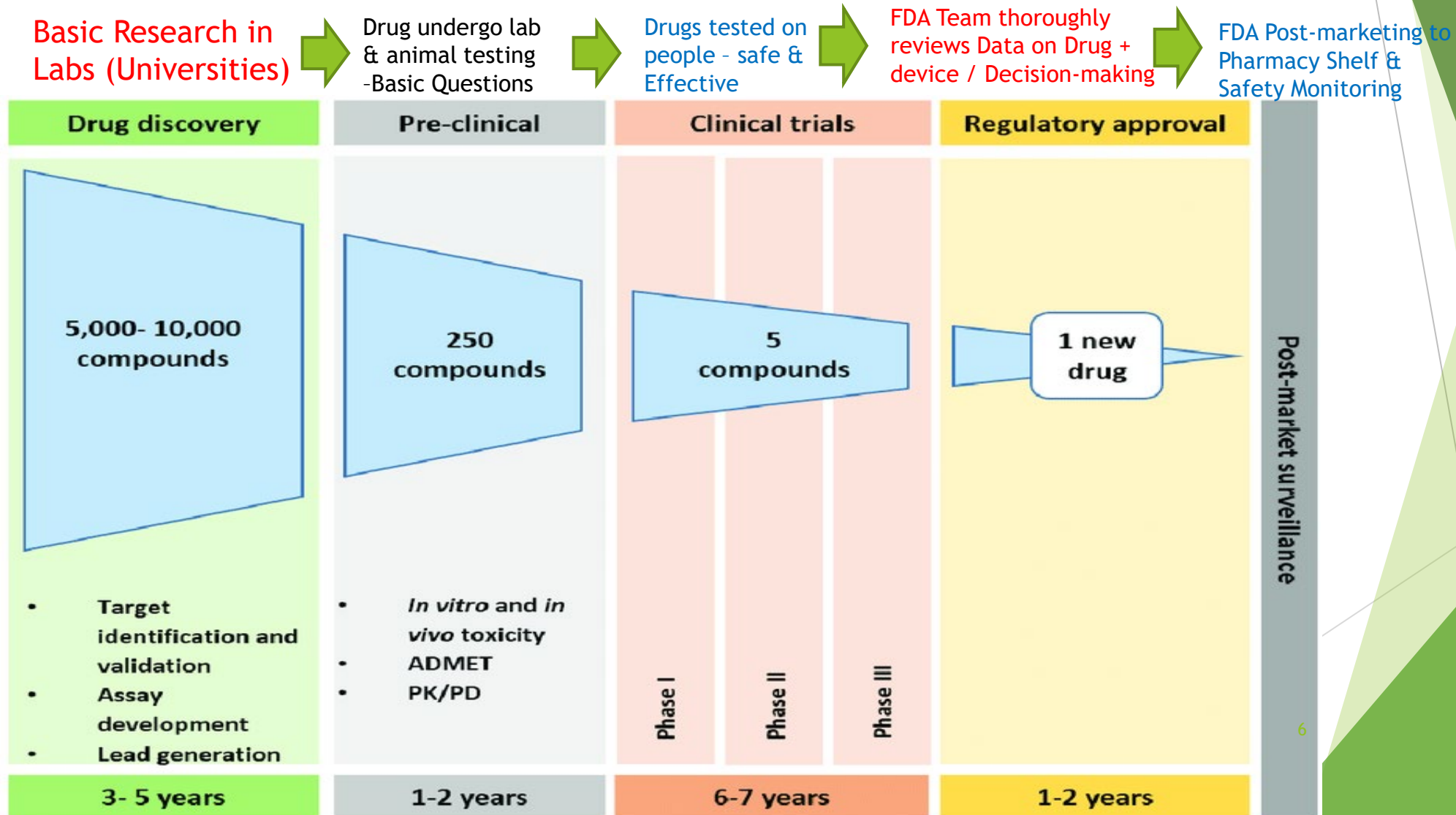
OVERVIEW OF DRUG / VACCINE DEVELOPMENT PROCESS

Drug / Vaccine Development Process

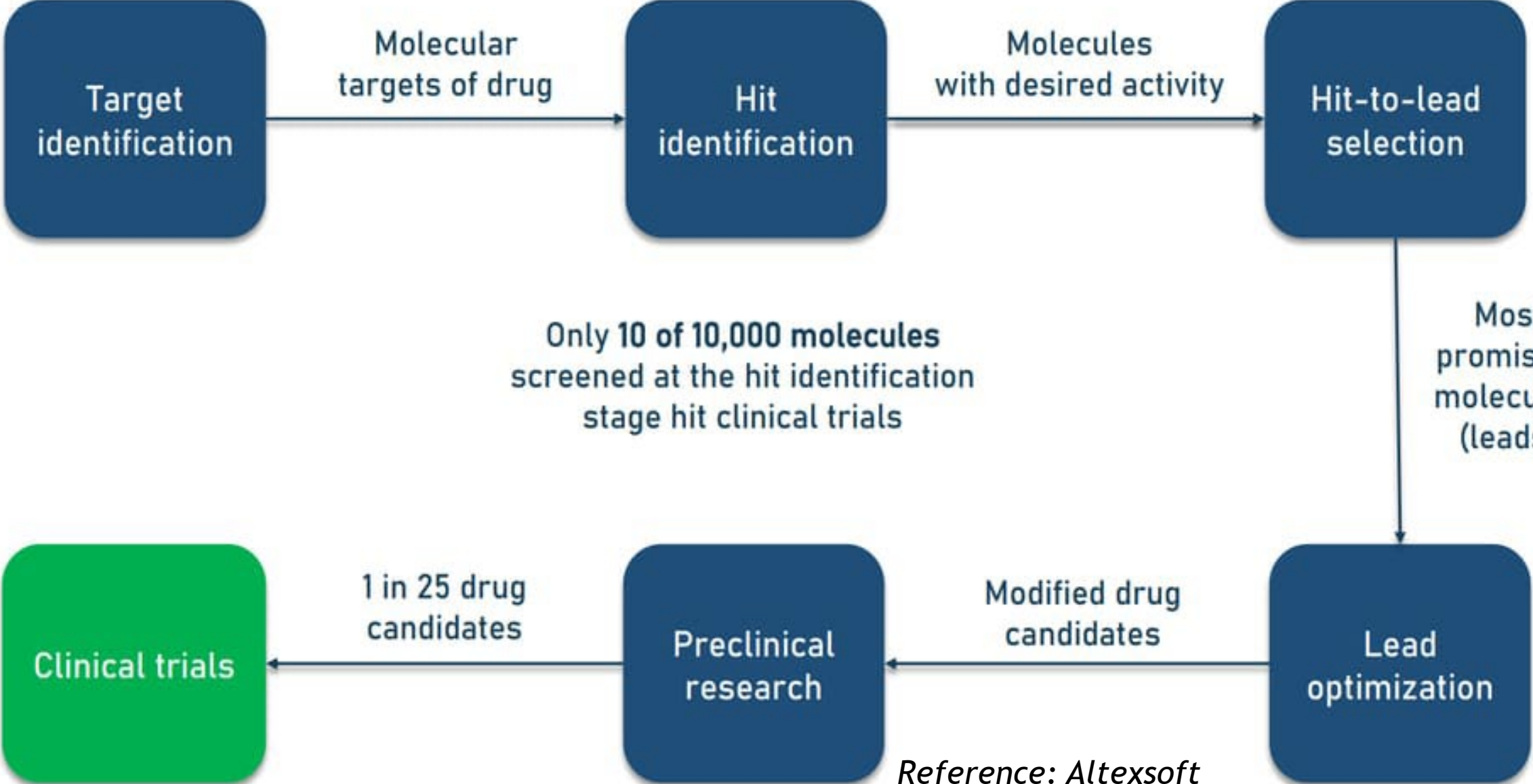
- Undeniably complex – **WHY?**
- From molecule discovery to FDA review and safety monitoring to commercialization
 - Many opportunities for things to go right or go wrong.
 - In 2022, the FDA approved 37 new drugs, or “novel” drugs.¹
- Overall, POS for NMEs -12 %
- Deemed a “success,” - New drug must make it through five specific phases:
 - 1. Discovery and Development,
 - 2. Preclinical research,
 - 3. Clinical research,
 - 4. FDA review, and
 - 5. Safety monitoring.



Overview Drug Development Process Flow

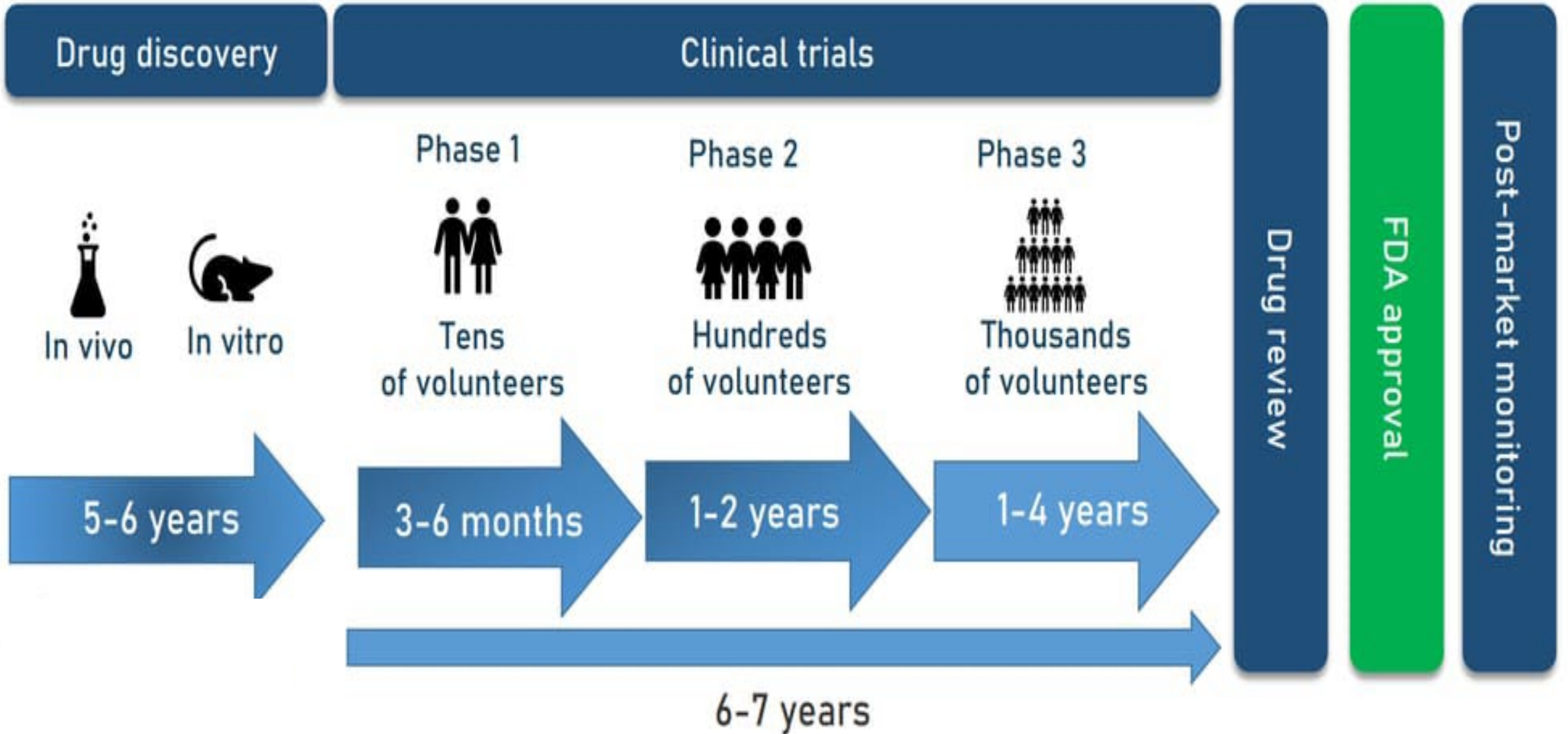


DRUG DISCOVERY PROCESS



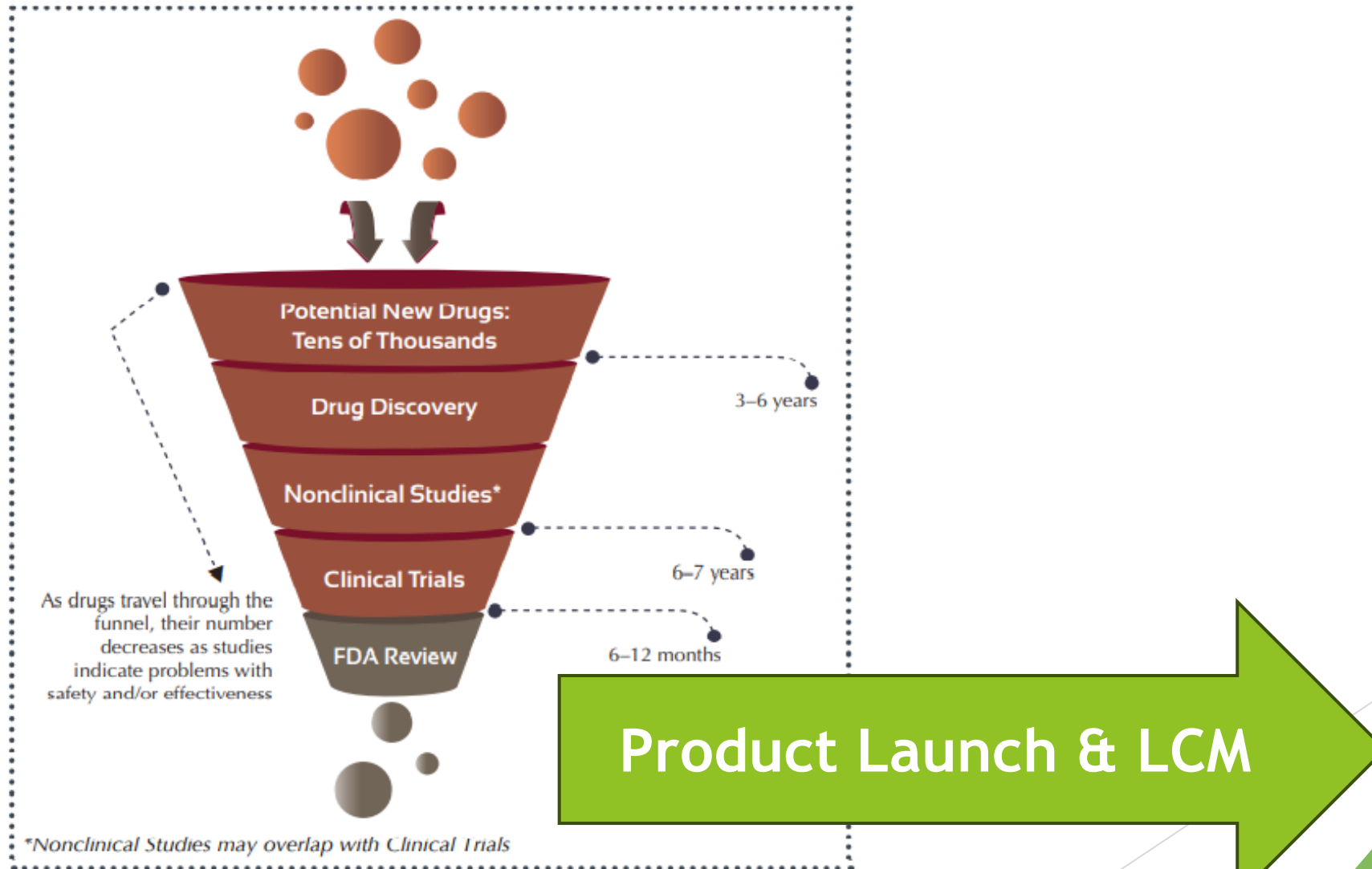
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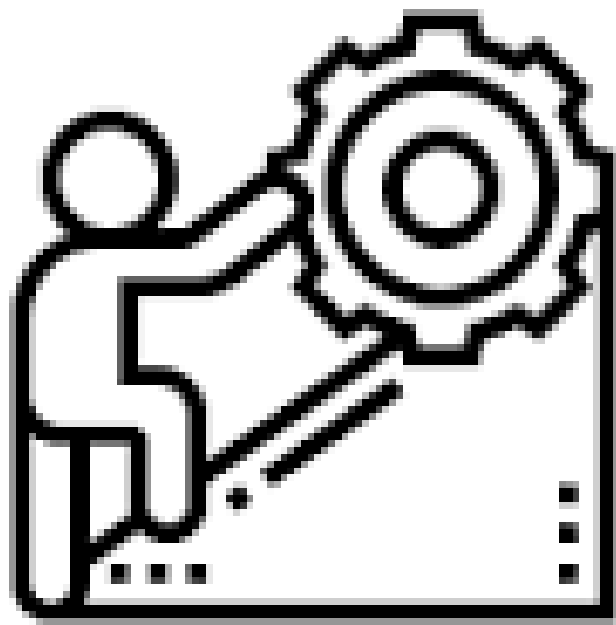
DRUG DEVELOPMENT STAGES AND TIMELINE



Drug Development Process Contd. - *From Discovery to Launch (Overall Perspective)*

EXHIBIT 1. DRUG DEVELOPMENT FUNNEL





OVERVIEW OF CHALLENGES IN DRUG / VACCINE DEVELOPMENT

Challenge Overview in Vaccine Development

Challenges may differ - Respective product and Parties involved

- Hurdles apply globally – especially in LMIC

Main Challenges in Vaccine Manufacturing:

- Cost of vaccine manufacturing
- Sustainable manufacturing
- Efficiency and tight timelines
- **Scale-up challenges in vaccine development**
- **Cold chain management**

Drug Development Team Members / Stakeholders

High Level Drug / Vaccine Development

Vaccine R&D → Manufacturing & QC → Supply Chain & Dissemination

- CMC Team Management
- Science submission management.
- Data science and modeling.
- Bioprocess technologies and engineering.
- Cell Culture | Fermentation Sciences.
- Purification process sciences.
- Dosage form design and development.
- Logistics and clinical supply
- Analytical Sciences Group
- Quantitative Sciences.
- MSAT
- Bioassay group
- Manufacturing Sciences

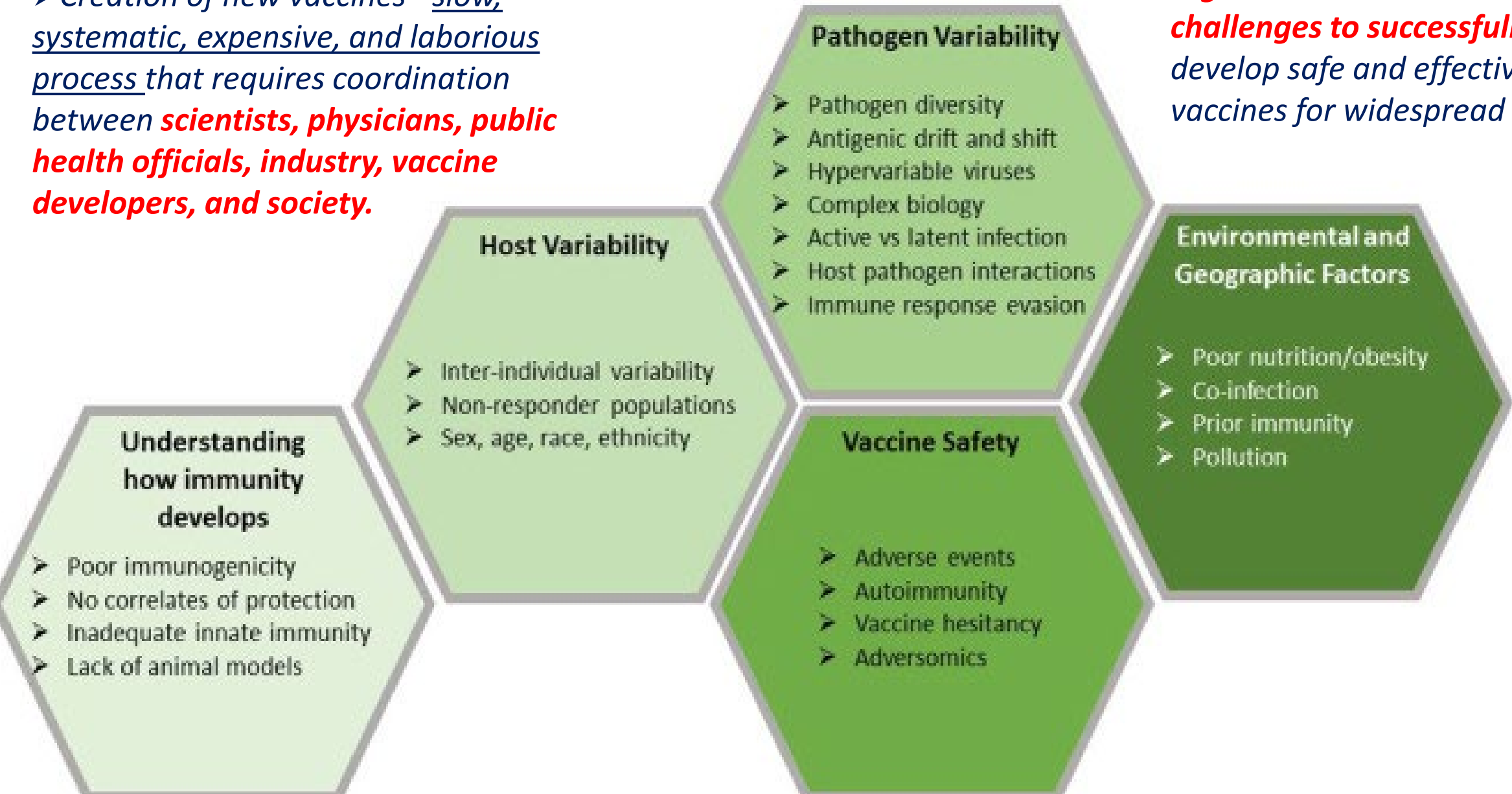
Teams and Responsibilities

- Project Management
- Medical Officer
- Pharmacology / Toxicology
- Statistician
- Clinical Pharmacology / Biopharmaceutics
- Chemists / Biologists / Microbiologists

Challenges of Vaccine Development

➤ Creation of new vaccines - slow, systematic, expensive, and laborious process that requires coordination between **scientists, physicians, public health officials, industry, vaccine developers, and society.**

➤ These shareholders **must work together to overcome the listed challenges to successfully develop safe and effective vaccines for widespread use**



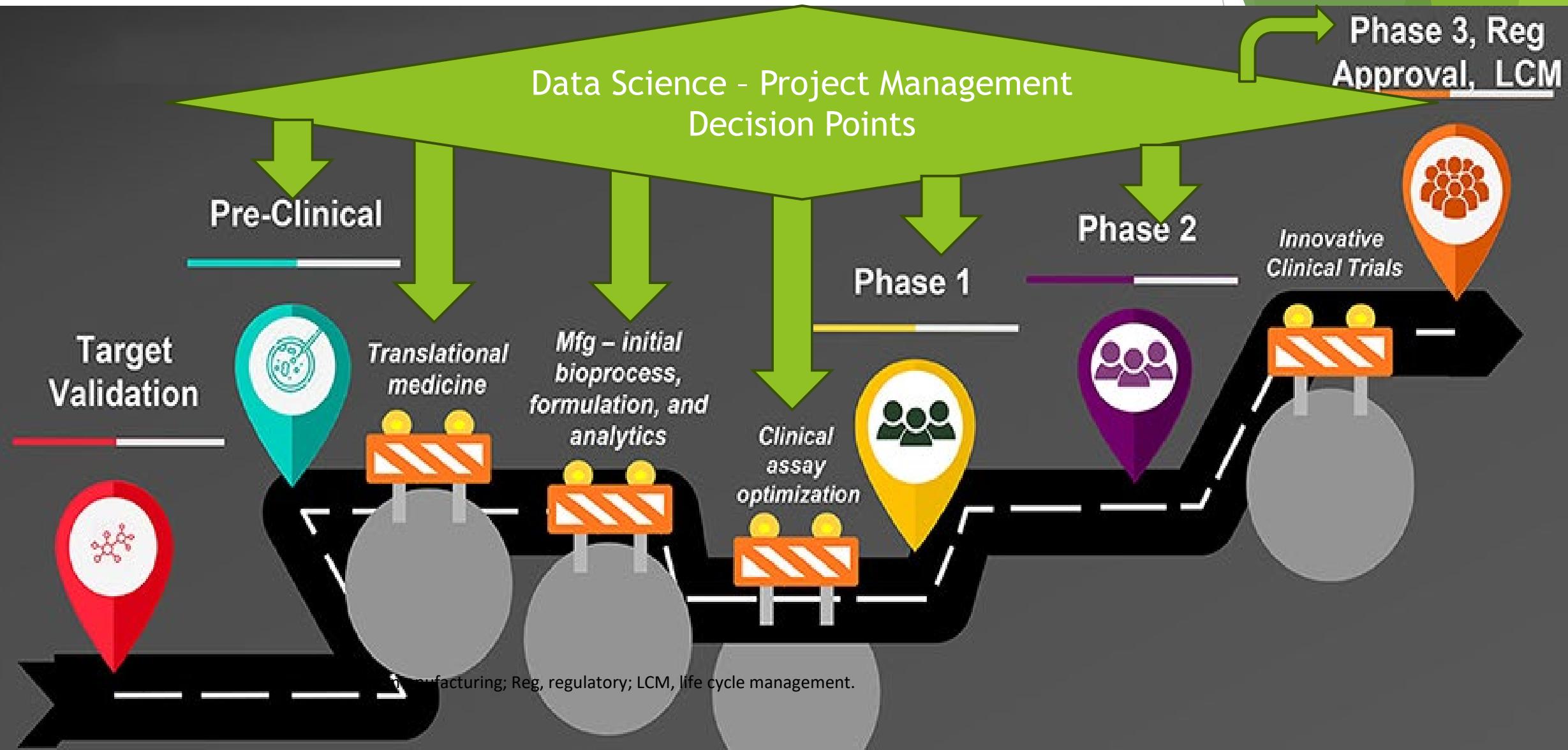


OPPORTUNITIES IN SUCCESSFUL DRUG / VACCINE DEVELOPMENT

Overview of Opportunities

- Role and Impact of Project Management
 - Application of Effective Project Management Tools - Regular & Advance Tools
- Team Collaboration
- Risk Identification / Assessment / Risk Management
- Use of Communication - C3 / 7Cs
 - Effective Communication
 - Collaboration
 - Compromise
- Project Management Governance - 3 Pillars
- Clear CMC Governance
- Data Governance & Application of Artificial Intelligence (AI)

Steps in Vaccine Development, Manufacturing, Regulatory & Lifecycle Management



Key Objectives / Questions?

- Align on objectives of the drug development and approval process?
 - a) Overarching goal: to bring more efficient and safer treatments to the patients as quickly as possible after a thorough medical evaluation
- What are the major activities that occur during:
 - a) the drug development and
 - b) approval process from nonclinical testing to market approval?
- What are the major elements and steps required to conduct a clinical trial?
- Role of Project Management - Communication / Clear Road Map: *Descriptive, Diagnostic, Predictive and Prescriptive for Effective & Efficient Decision-making*

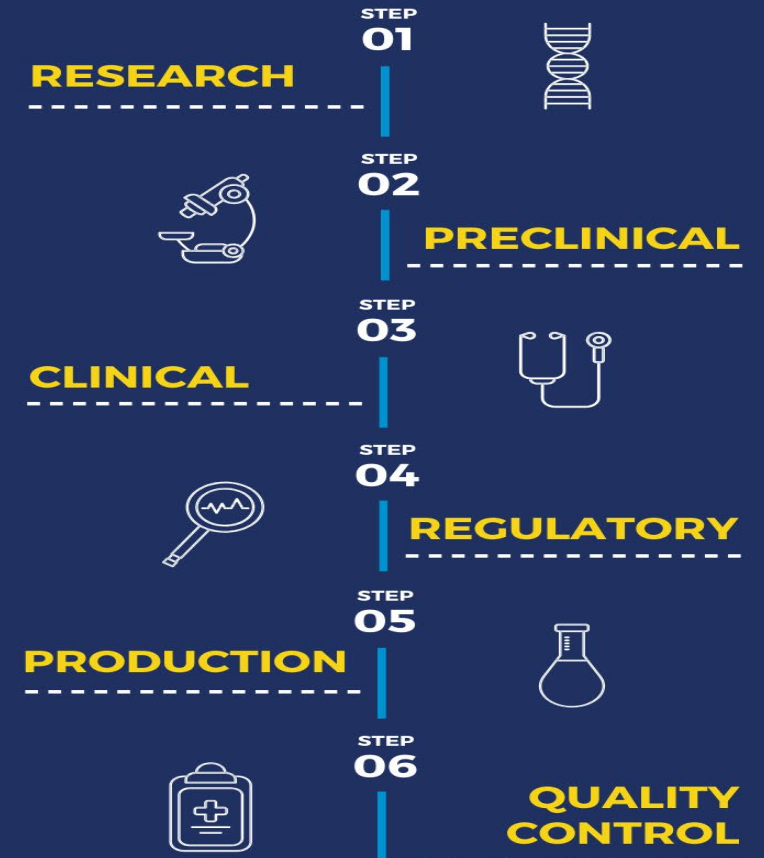
Ensure Roadmap to Drug Development

Identify the Objectives & Strategies of Different Stakeholders / Functions

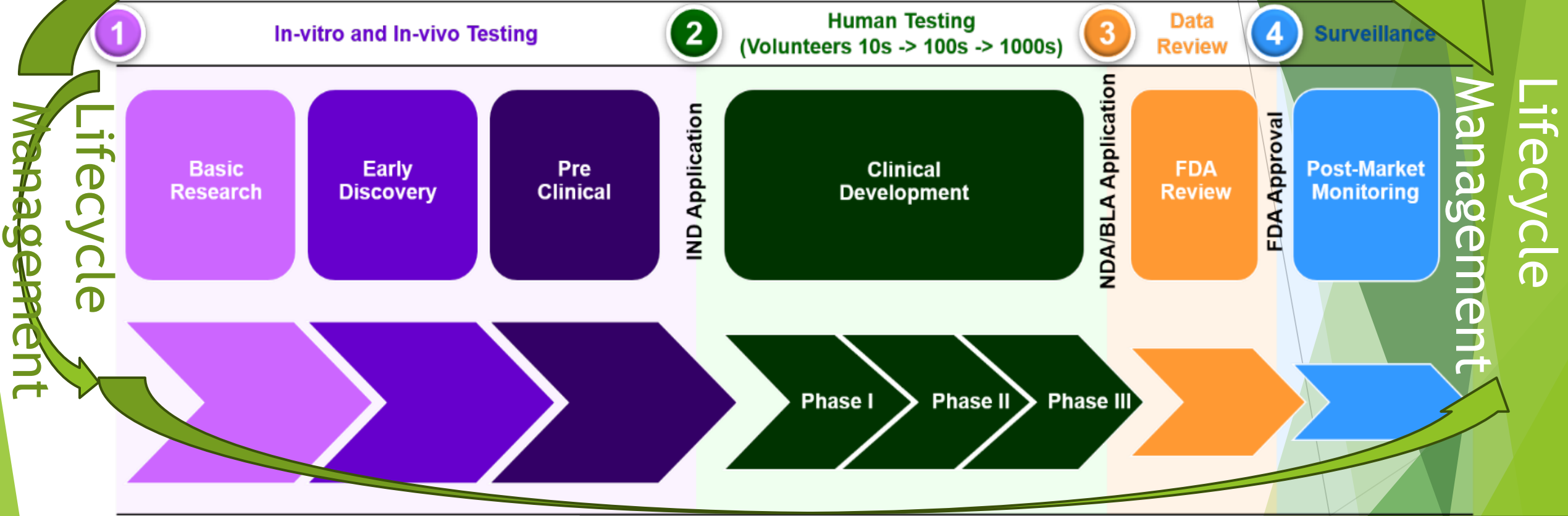
- Formulation Strategies
- Analytical Strategies
- Regulatory Strategies
- Commercial / Marketing Strategies
- Project Management Strategies, Tools & Governance
- Communication / Clear Road Map: Descriptive, Diagnostic, Predictive and Prescriptive for Effective & Efficient Decision-making



WHAT ARE
THE **STEPS** TO
DEVELOPING A
VACCINE?



ROADMAP - Overview of Drug Phases – Complex Processes



➤ **Complexity includes:**

- Preclinical testing,
- investigational new drug (IND) applications, and
- completed clinical testing before marketing approval from the FDA.

Complexities drug applications are seen in:

1. New Drug Application (NDAs) or
2. Biologics license applications (BLA)

Review Process

1. Applications and
2. Then drug performance is reviewed comprehensively before approval, resubmitted to regulatory agencies for post-marketing studies

Role of Project Manager in Each Phase of Development

- Preclinical Stage: Selection of Antigens
- Screening and evaluating the effectiveness of the vaccine
- Regulatory approval and licensure
- Scaling up the manufacturing process
- Quality control and safety checks
- Packaging, storing, and shipping of the vaccine.



Project Management must ensure effective communication across the entire Phases at different level of involvement

Critical Factors in Addressing Vaccine Development / Pharmaceutical Development Challenges

- Roles of Project Managers
- Role of Stakeholders
 - Subject Matter Experts
 - Formulation Scientists
 - Analytical Development Scientists
 - Regulatory Affairs (RA)
 - Clinical Development
 - Quality Assurance (QA)
 - Pharmacokinetics / Pharmacology
 - MS&T
- Team Communication
- Key Business Process
- Management / Leadership / Sponsors



Key: PjM - *Project Management (Project Manager)*



PROJECT MANAGEMENT PERSPECTIVE

Project Management Perspectives



Complexities of Project Management



Challenges of Project Management



Team Members & Stakeholders of Project Management



Governance in Project Management

Solutions to Challenges: Tools of Project Management & the Use of Data Science & AI

Proponent and Alignment in 3 Governance - PjM / CMC / Data

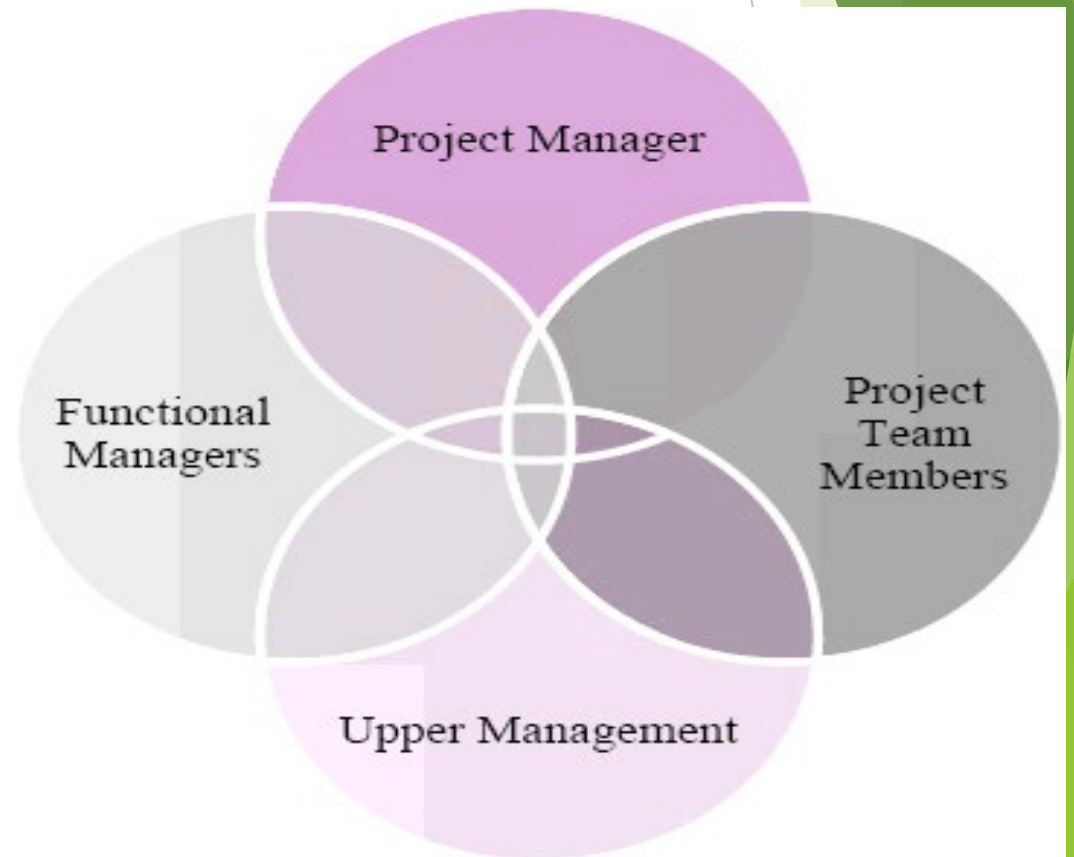
Project Management Governance

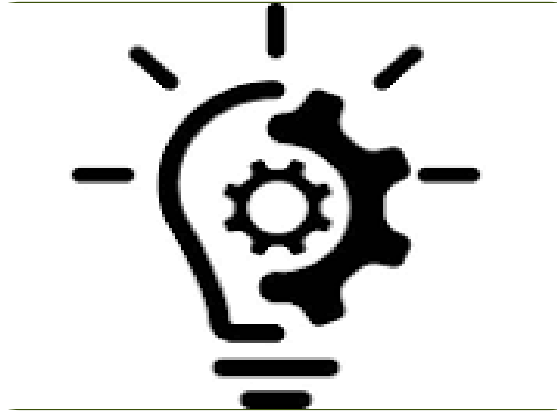
- Project Management Governance - 3 Pillars
 - Structure - proper governance structure, decision-making authorities and committees
 - People - Project team members with right competences
 - Information - Accurate, timely and relevant data
 - Robust data management
 - Proactive risk assessment

Complexities of Project Management

- Known Risks – (Known – Unknown)
- Unknown Risks (Unknown – Unknown) or Unforeseeable Risks
- Interdependencies between Elements of Challenges
- Type of Organizations
- Regional factors: Low- and Middle-Income (LIMC) Areas (e.g. Africa, Developing countries)

Components of Project Management in Matrix Organization





CHALLENGES OF PROJECT MANAGEMENT

Major Challenges for Biotech & Pharma Project Managers & Project Management

- Scope management
- Navigating resource management
- Project planning, execution, and monitoring
- Cross-functional team leadership / management
- Risk management
- Timeline and budget planning / management
- Stakeholder management
- Management of regulatory and compliance strategies

The interdependencies between these elements make it even more complex

Challenges in Project Management Contd.



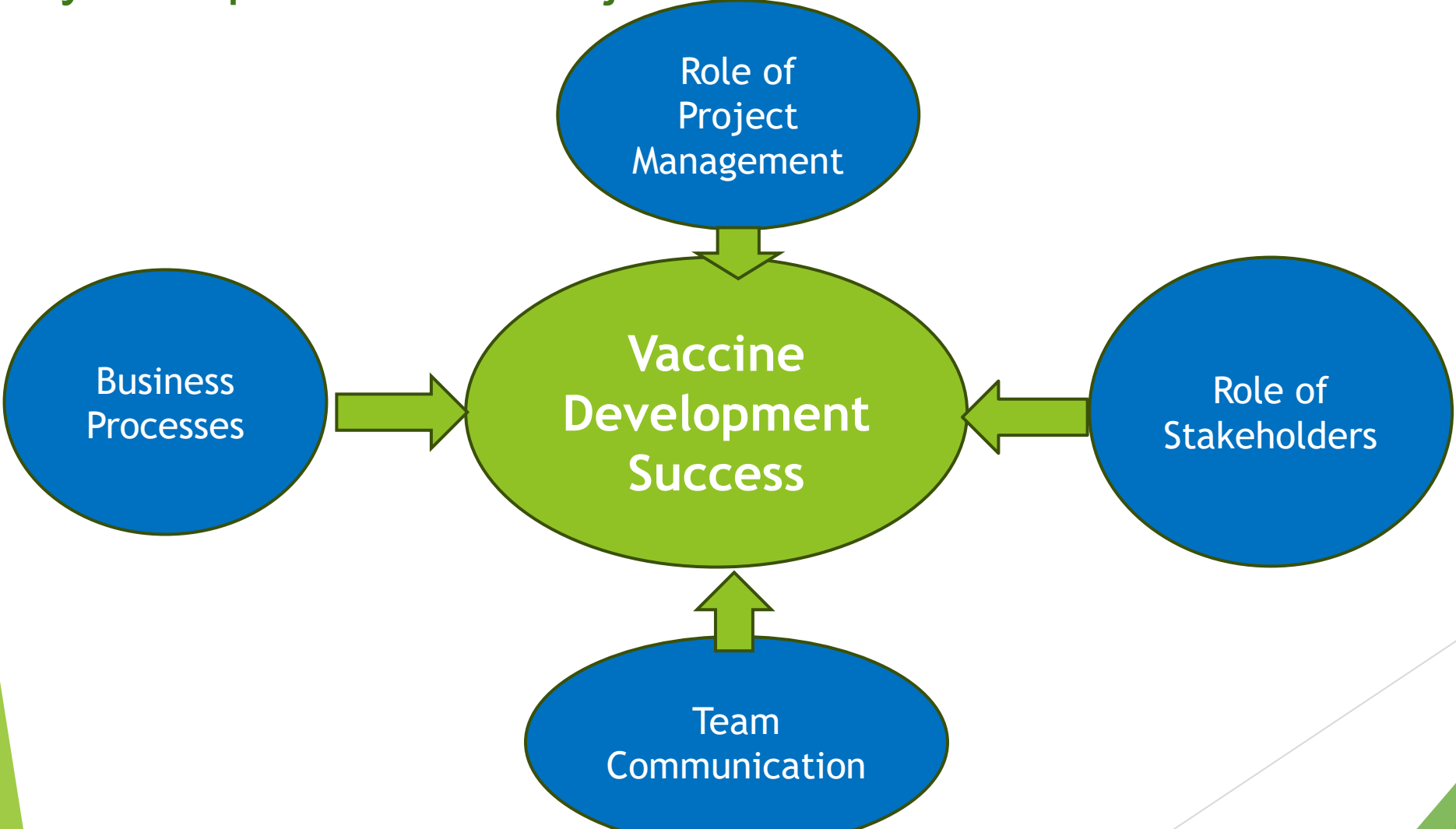
- Breaking Down Silos
- Team management Scheduling Compliance and approvals
- Institution processes
- Cultural differences
- Customer management
- Seeing the full picture of your portfolio
- Environmental safety

CRITICAL SUCCESS FACTORS

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Critical Success Factors / Key Components of Vaccine Project Success

Key Components of Project Success



Project Management Expectations - Success Factors in Vaccine Development

Key Deliverables

- Project Management Base
- Project Portfolio Analysis
- **Communication Plan**
- **Risk Management Plan / Identification / Management Strategy**
- Project Charter
- Project Management Plan
- Workflow Management

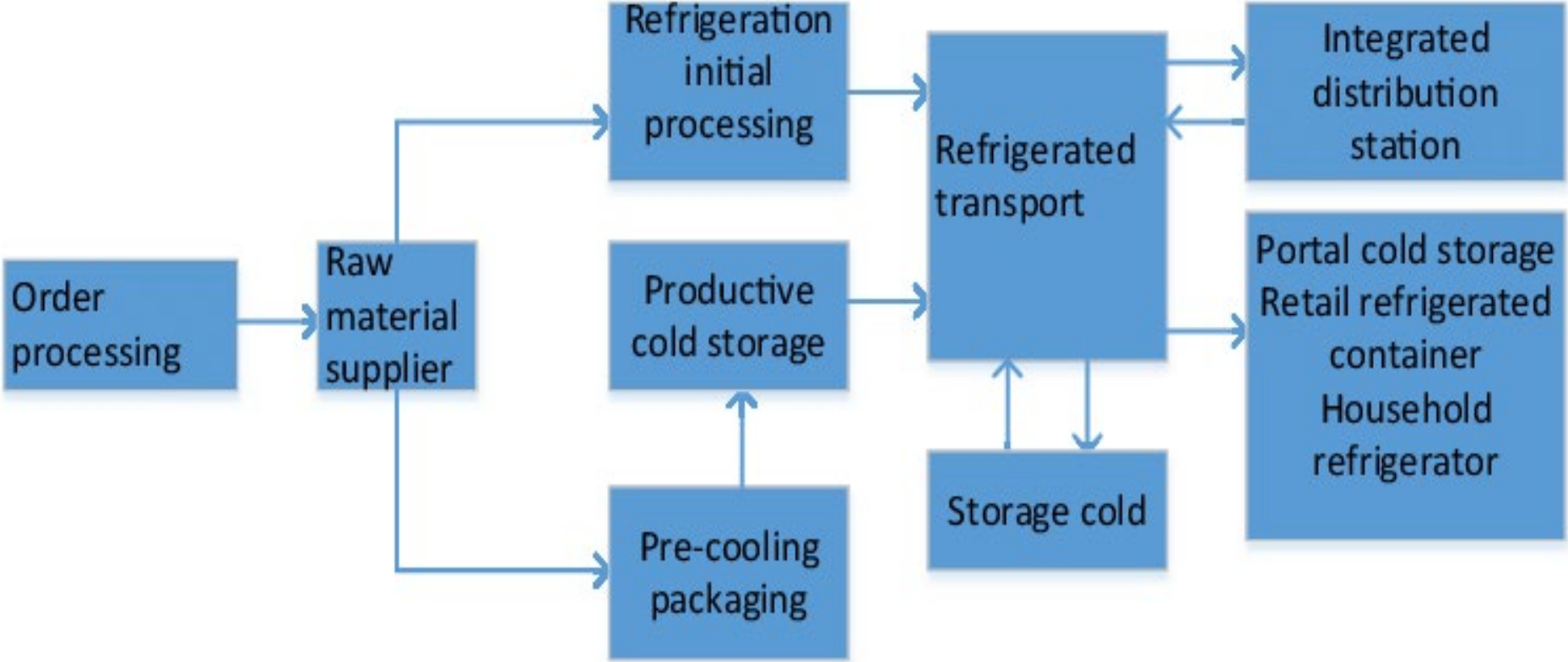
Key Deliverables

- **Effective Governance**
- Procurement Plan
- Quality Assurance Plan
- Work Breakdown Structure
- Earn Value Analysis
- Status Reports
- Lessons-Learned

Project Management in Clinical Trials

- Critical Project Management Decision Points
 - Phases I
 - Phase II, or
 - Phase III

Cold Chains Management - Critical for Project Management





Opportunities & Strategies for Solutions to Challenges in Drug / Vaccine Development

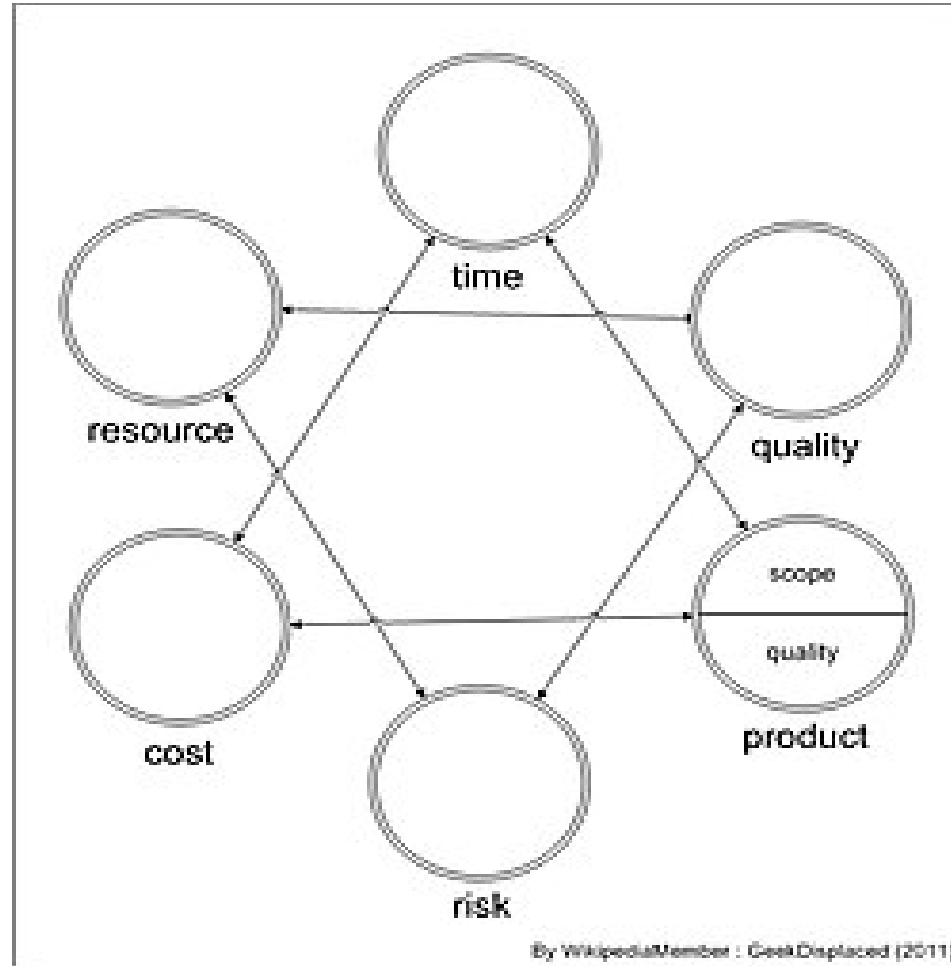
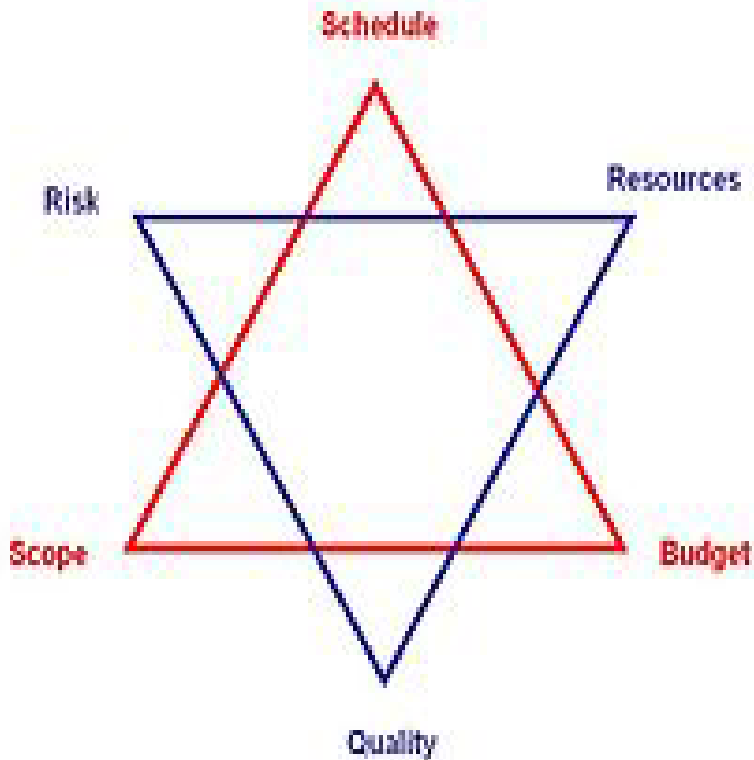
Opportunities in PjM Perspectives

- Identify & Understand Constraints
- Gap Analysis / Define Gaps / RACI
- Apply Project Management tools & Advanced Tools
 - Data Science - Agile, Scrum, RAID Log (Risks, Assumptions, Issues, Dependencies), Risk Register, Matrix, RACI, CBA, Feasibility Studies, etc.
 - Application / “Enforcement” of Data Analytics ➡ Data > Identify Structure > Capture > Structured vs unstructured > Document > digitize - Usage readiness
- Application of Artificial Intelligence (AI)
 - **PM ensures RACI: Descriptive, Diagnostic, Predictive and Prescriptive for Effective & Efficient Decision-making**
 - **PM initiates and ensure QC of AI-generated information / Data / Packaging**

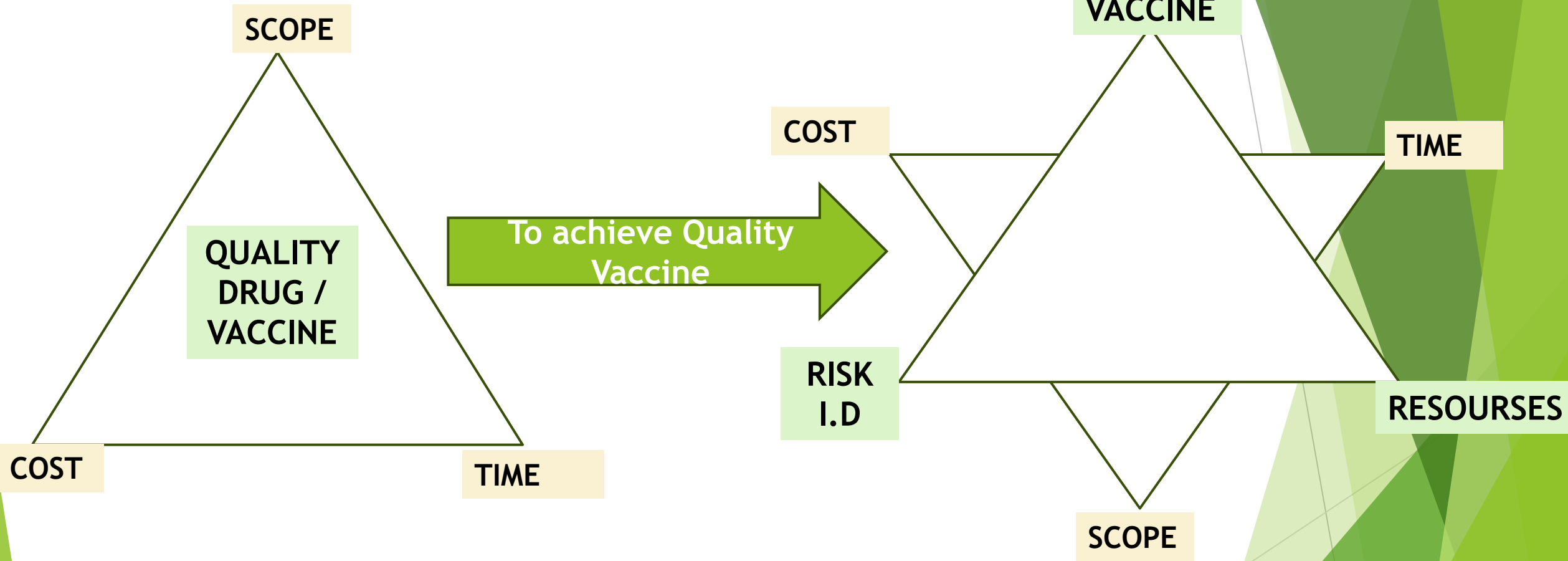
Project Management Constraints

Traditionally the Project Constraint Model recognized three key constraints; "Cost", "Time" and "Scope". These constraints construct a triangle with geometric proportions illustrating the strong interdependent relationship between these factors. If there is a requirement to shift any one of these factors, then at least one of the other factors must also be manipulated

"Triple Constraint" in Project Management



Project Management Triple Constraints



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**MITIGATION OF CHALLENGES
&
NEXT CHAPTER OF INNOVATION**

Effective Project Management Tools - Mitigate Challenges

- Risk Management
- Communication - / Clear Road Map
- Project Management Governance
 - Application of QbD-SixSigma
 - Tools for Data Science
 - Manage & Ensure Data Governance
- Use of Artificial Intelligence (AI)
 - *Descriptive, Diagnostic, Predictive and Prescriptive for Effective & Efficient Decision-making*
- Tools for Data Science
 - Agile Methodology
 - Scrum, etc.
- CMC Governance
- Data Governance
- Use of Emotional Intelligence (EI)
- Communicate, Collaborate & Align with SMEs to ensure Compliance

Governance & its Strength in Development Successes

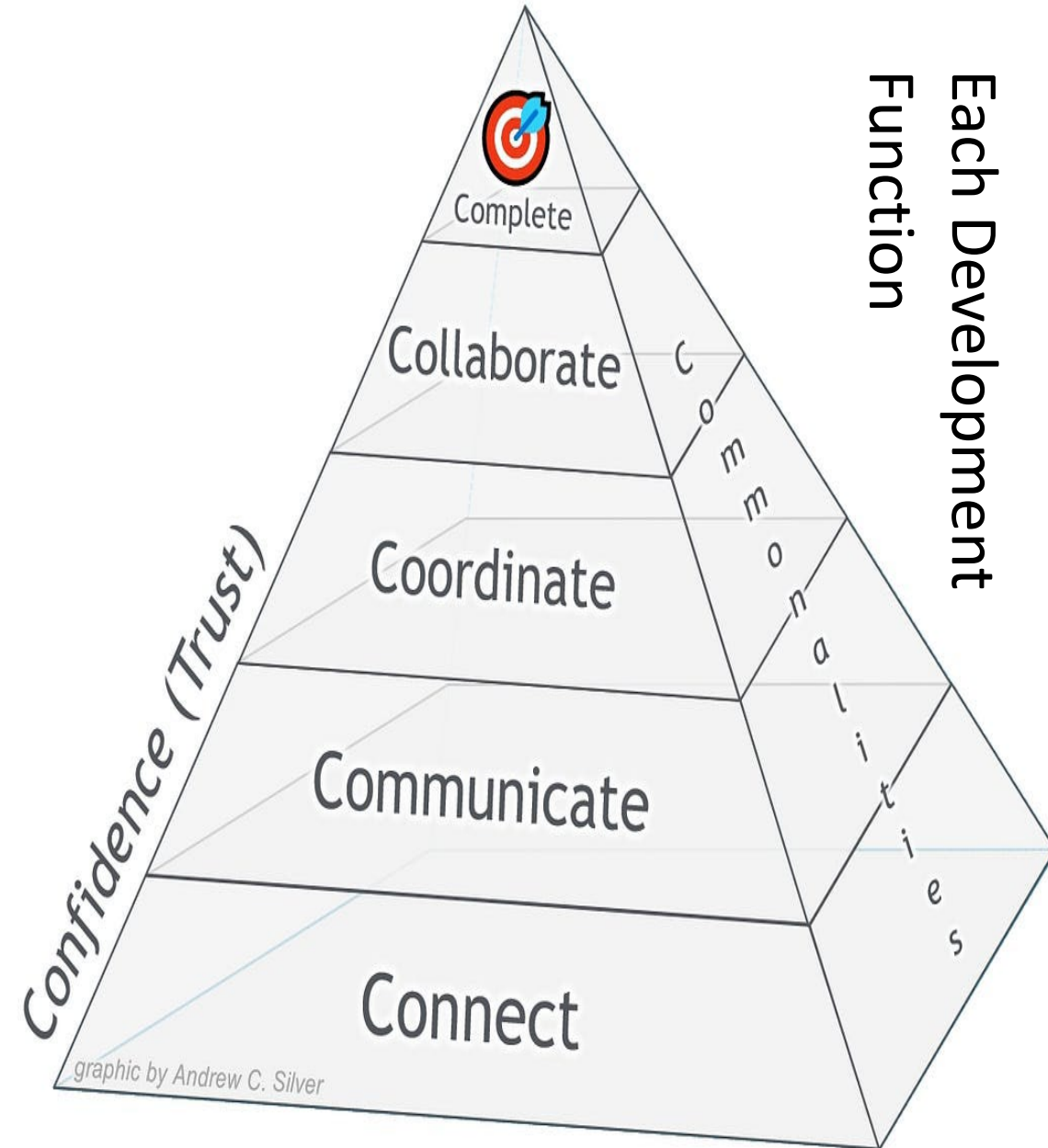
- Project Management Governance
- CMC Governance & Ecosystem
- Data Governance & Integrity
 - Formal plan for the way an organization manages company data – Rules (Accountability & Compliance).
 - Data integrity + Data Governance + Data Culture > Data Quality
 - Structured Data & Timeline
 - **PM leads Data-centric thinking and behavior**

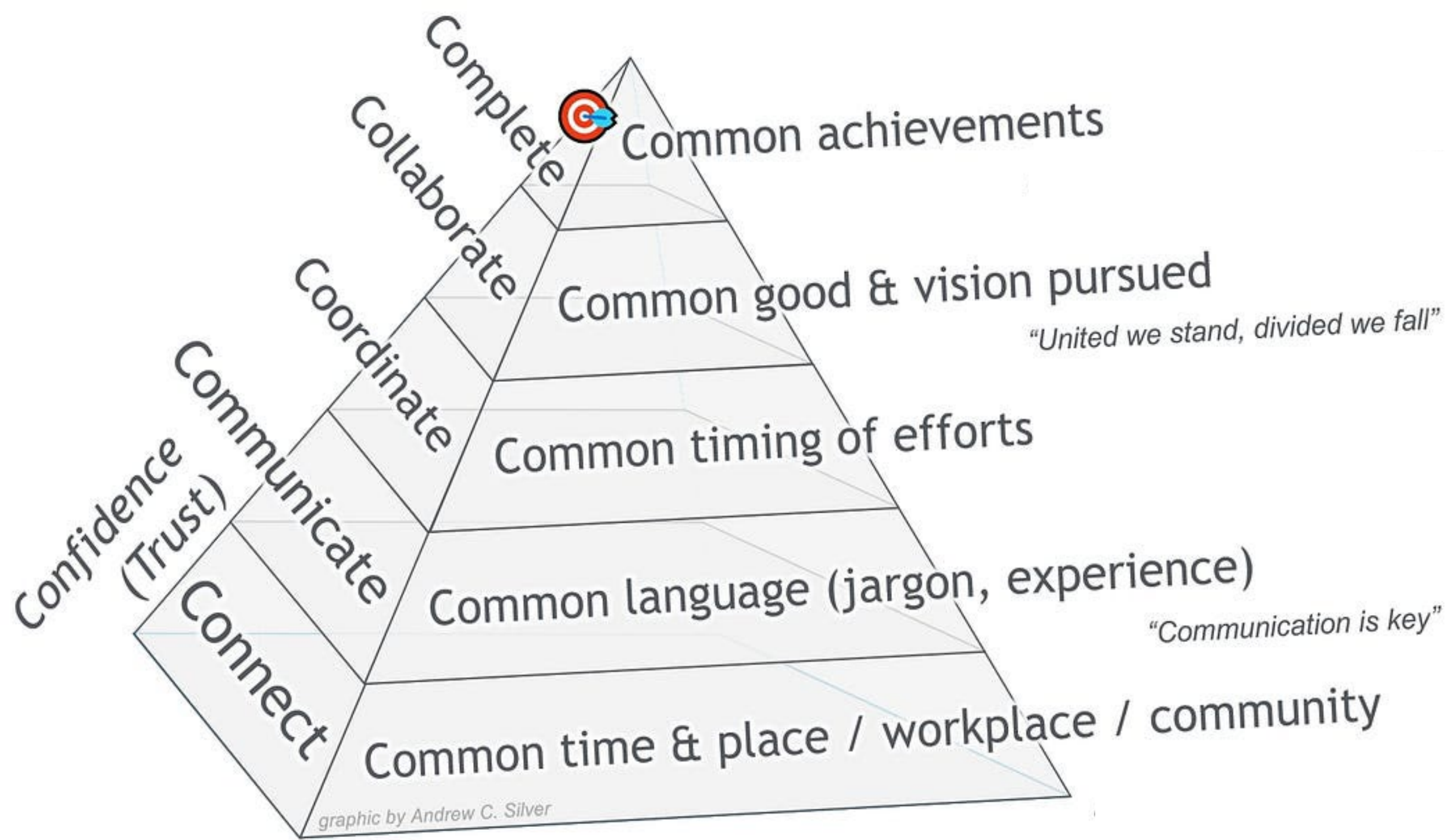
Challenge Solution - Successful Toolkit of Project Management

- Cultivate a process of collaboration by tending to each element of the 7 C's and in the correct order.
- *Intelligible Communication* facilitates *coordination*.
 - *Coordination* lays the groundwork for *collaboration*.
- **Collaboration** - makes many large objectives manageable. Action is needed to *complete* the Project objectives.
- Avoid a Linear process - Some iteration and looping is inherent in the flow of communication.

Value of the 7 C's:

1. Highlighting the prerequisites of **commonalities**, **confidence (trust)**, and the need to **connect**
2. Explaining the **flow** (sequencing) needed to build collaborations and complete goals
3. Appending the need to **complete** (achieve) goals,
 1. Mitigate delays from the **knowing-doing gap**





Project Management Strategies in Innovation - Risk Management, AI, EI & New Technologies

Define / Identify Risk - Using QbD

- Locate Risk & Opportunity
- Prioritize Risk with strategy
- Innovate safely, consistently and efficiently

Review Barriers / Manage by QbD

- Identify Barriers
- Measure progress and refine your solution

Understand Goals and Objectives

- Identify and prioritize the goals and objectives
- Generate (Team) Innovative solution
- Measure the Solution

- Incubate and test the solution
- Pilot the solution with Stakeholders
- Measure progress and refine your solution

Application of Artificial Intelligence (AI)

Application of Emotional Intelligence (EI)

Investment in New Technologies

Impact of Artificial intelligence (AI) Project Management / Next Chapter Innovation

- Risk Management
- Predictive analytics
- Decision-making
- Resource allocation
- Task Scheduling and Automation
- Time Tracking
- Improved collaboration with team members and stakeholders.
- Reduced risk of delays and cost overruns
- Cost Estimation:
- Document Management:
- Communication Enhancement:
- Quality Control:
- Performance Monitoring:
- Personalized Recommendations:
- Natural Language Processing (NLP):
- Automation:
- Scalability

Summary / Key Takeaways



- Drug / Vaccine Development Process – Very Complex
 - Traditional drug development process can take about 10-15 years with 90% of drug candidates failing.
 - **Development costs from about \$314 million to \$2.8 billion USD.**
- Major challenges in Vaccine Development and Manufacturing, especially in LMICs due to
 - Complexity of Drug Development Process, Costs & sustainability of manufacturing, tight timelines, Scale up challenges, cold chain management and Lifecycle Management
- Effective Management and Implementation of the Opportunities yields Successful Drug / Vaccine Development
 - PjM Critical Factors in Development - C3 and 7Cs – Communication / Collaboration/Compromise
- **Data Science** relies heavily on Project Management techniques, tools & methodologies
 - Effective generation / Identification of Structured data facilitates Innovation
 - AI, EI & New Technologies

Thank You

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BACKUP

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Bucket List of Challenges Facing Vaccine Development Efforts

- High (and increasing) costs for vaccine development (~\$700 million–\$1 billion)
- **Vaccine hesitancy**
- More stringent safety requirements
- **Societal expectations of 100% efficacy**
- Need to maintain cold-chain for vaccines
- Increasing requirements for single dose efficacy
- Need for rapid response to global outbreaks
- **Limited number of vaccine manufacturers (more so in LMIC)**
- Product development time (typically ~10 years)
- Current pathogens require more complicated vaccines
- Low efficacy of some licensed vaccines
- Business models prioritize vaccines by market potential, not by public health need
- Aging world population that respond poorly to most vaccines (immunosenescence)
- Limited number of approved and acceptable adjuvants
- **Concurrent health problems in developing world that compromise immune response (nutrition, co-infection)**
- **Incomplete or inadequate understanding of biology, pathogenesis, and/or immunology of emerging pathogens**
- Inability to properly attenuate pathogens OR risk of reversion to wild type organism
- Humoral immune responses do not always correlate with protection
- Inappropriate/harmful immune response (formalin-inactivated RSV products) or enhanced disease upon re-infection (Dengue)
- Inadequate durability of immune response (ex. Pertussis)