

Clinical Research Operations Project Management in Today's Pharma Industry

By: Karen Correa, PhD

Vice President, Head of Global Clinical Operations at Takeda Pharmaceuticals

Disclaimer: The views, information, or opinions expressed herein are solely those of the presenter and do not necessarily reflect or represent those of Takeda Pharmaceutical.

Growing Demand for Clinical Research Professionals

According to a report by the Bureau of Labor Statistics, employment of medical and health services managers (which includes clinical research professionals) is projected to grow **18 percent** from 2020 to 2030, much faster than the average for all occupations.

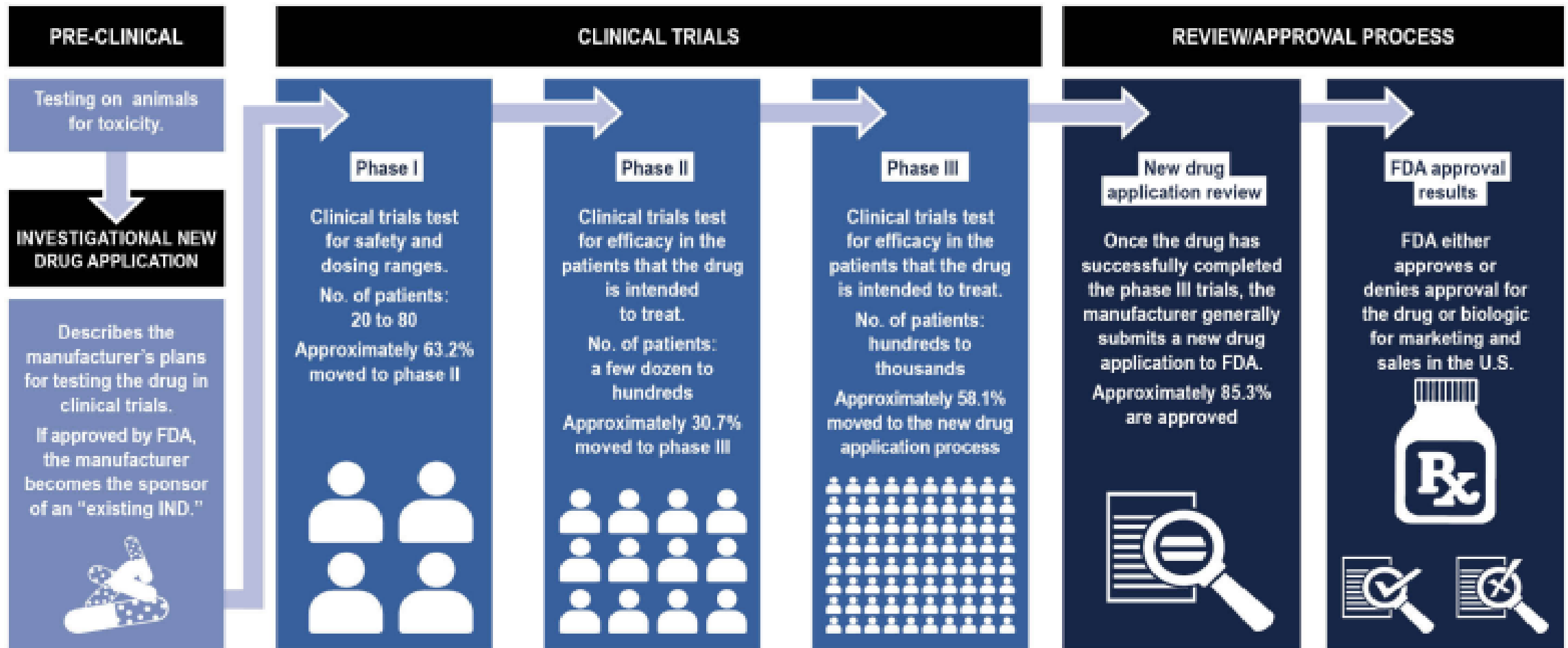
Driving this demand

- Aging population, increasing prevalence of chronic diseases, and the need for new treatments and therapies
- Potential for high salaries and job security (According to a survey by the Association of Clinical Research Professionals (ACRP), the median salary for clinical research professionals in the United States is \$120,000 per year)
- Opportunity to make a difference in patients' lives by playing a critical role in developing new treatments and therapies that can improve the health and well-being of patients around the world

Agenda

- ▶ Industry Overview
- ▶ Life Cycle of a Clinical Trial
- ▶ Current Clinical Development Trends
- ▶ Education and relevant experience
- ▶ Personal Branding
- ▶ Clinical Research Path
- ▶ Project Management in clinical research
- ▶ PM skills for success
- ▶ A day in the life of PM
- ▶ Technology and Innovation Project Management Tools
- ▶ The World of Clinical Trial Project Management

Figure 1: Food and Drug Administration's (FDA) Typical Drug Development and Approval Process



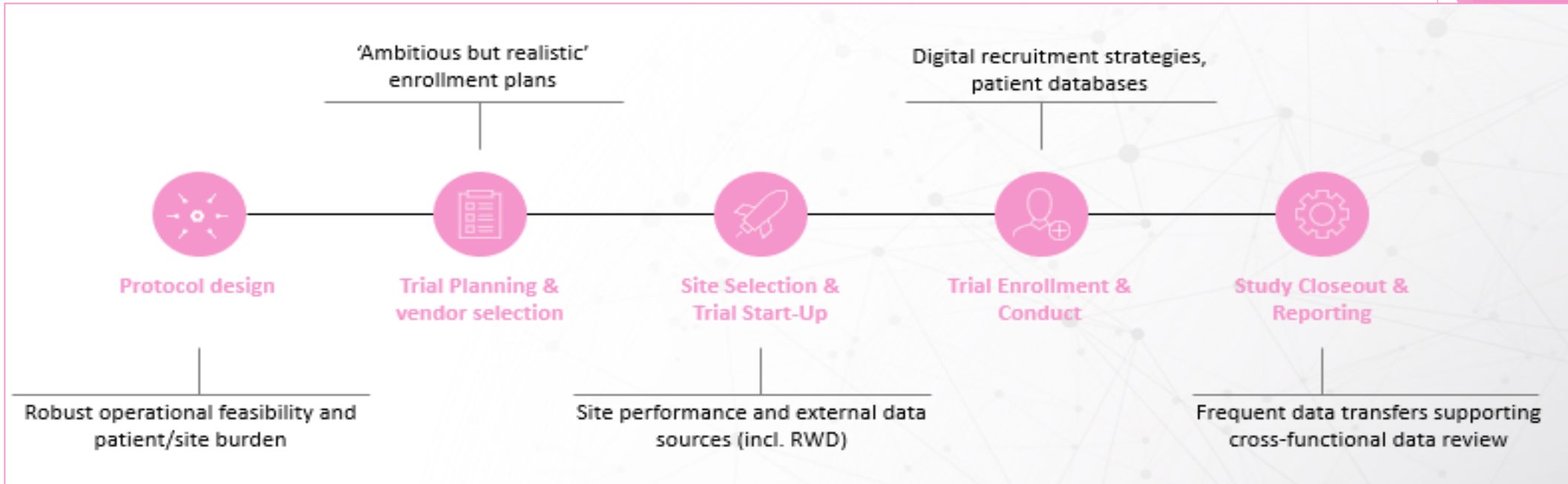
Source: GAO analysis of FDA data and a 2016 collaborative study by Biotechnology Innovation Organization, Biomedtracker, and Amplion.* | GAO-17-564

Clinical Development, also called Drug Development, is a blanket term used to define **the entire process of bringing a new drug or device to the market**. It includes drug discovery / product development, pre-clinical research (microorganisms/animals) and clinical trials (on humans).

Note: According to FDA officials, there can be wide variation in the number of patients involved in the different clinical trial phases, and, when a new drug is being tested for a life-threatening ailment, the drug development process may be expedited by going through only one or two phases of clinical trials before an application is submitted to FDA for marketing approval.

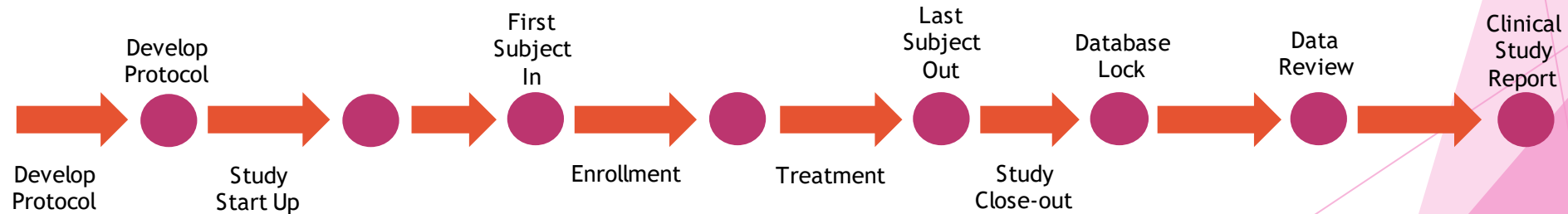
*David W. Thomas et al., *Clinical Development Success Rates 2006-2015* (Washington, D.C.: BIO,

Life Cycle of a Clinical Trial



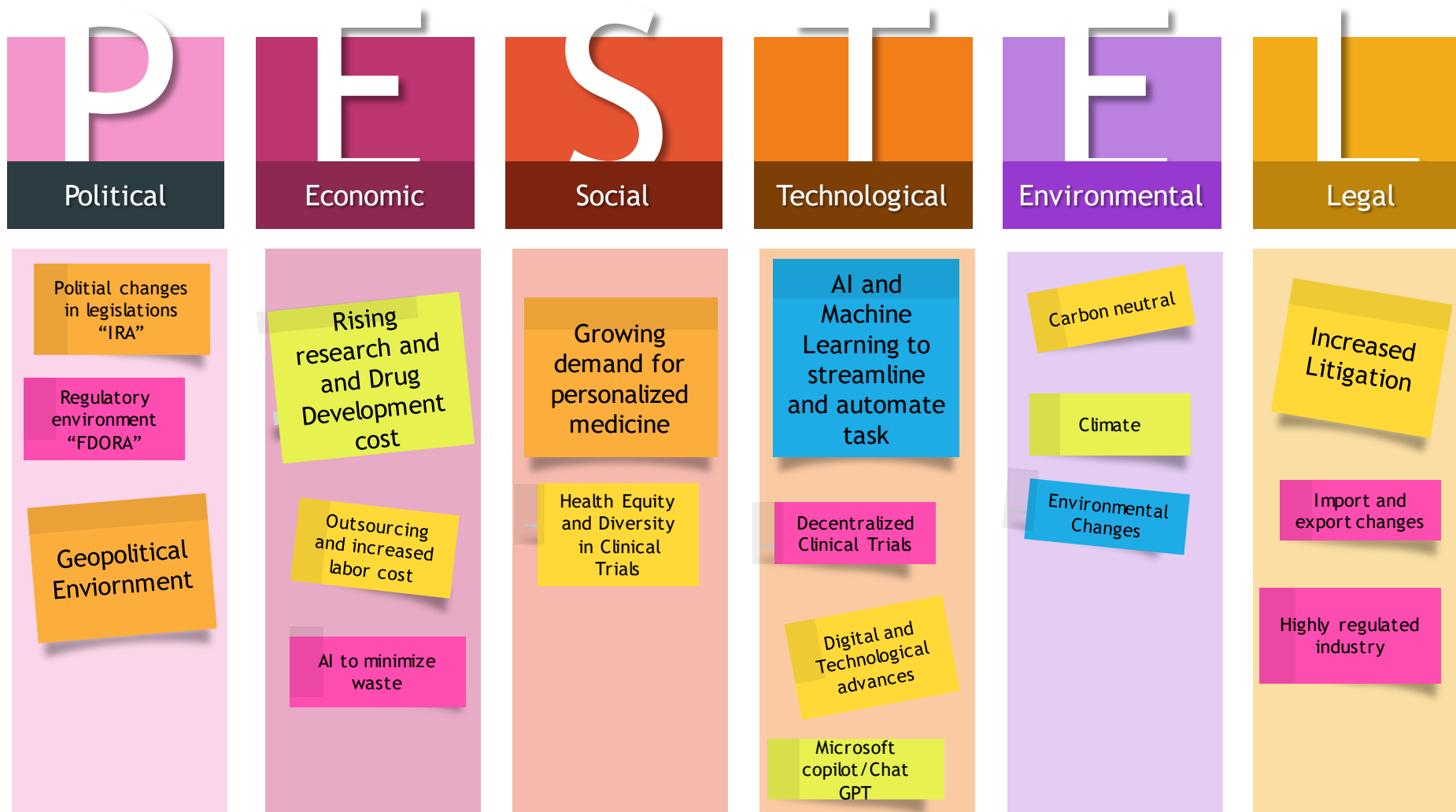
Clinical trial pathway from development of the clinical protocol in start up through to the report of the clinical study

Example of Phase 3 Pivotal Study



- Milestone
- ➔ Task

PESTEL Analysis - Current Clinical Development Trends



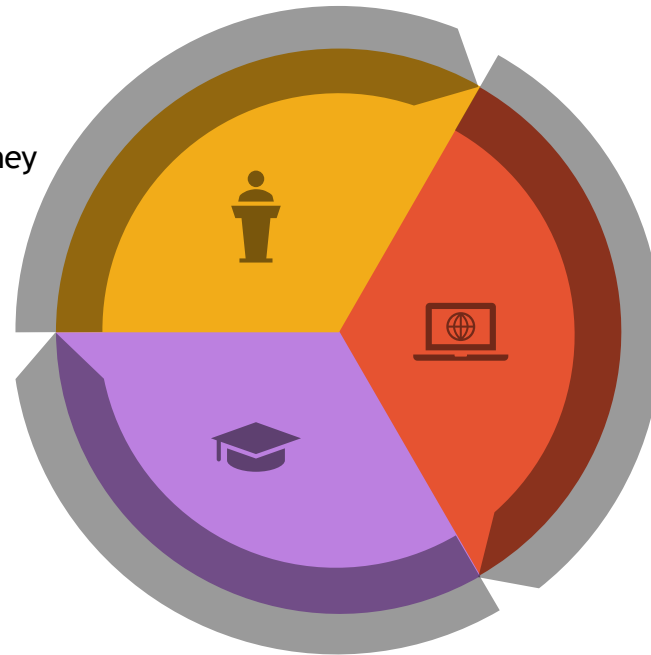
Education and Training

CERTIFICATE AND EXPERIENCE

Society of Clinical Research Associates (SoCRA)
Association of Clinical Research Professionals (ACRP)
Clinical Research Certificate Programs
*Add license & certifications to linkedin data suggest they receive 10% more followers

EDUCATION

Bachelor's Degree in life sciences, nursing, biotechnology, public health, biology, chemistry, medical technology, or a similar field, Advanced Degree MS, MPH, MBA, PhDs, PharmD



FREE TRAINING PROGRAMS

<https://ocreco.od.nih.gov/courses/ipocr.html>
<https://gcp.nidatraining.org/>
<https://www.pharmalessons.com/free-courses/>
<https://globalhealthtrainingcentre.tghn.org/>
[Job Training to Close the Opportunity Divide | Year Up](#)

Personal Branding



LinkedIn

Headshot, background, about, connect with recruiters and talent acquisition roles, review posts and comment, follow and subscribe to pharma media; Fierce Pharma, BioPharma Dive, PharmaTimes, Clinical Leader, FirstWord, Pharma News

Network

ACRP, SOCRA, DIA, ICR; Webinars, Conferences



Resume

Move from roles and responsibilities to achievements, accomplishments and results achieved, present transferable knowledge

Interview

Study the Job Description, Concise Elevator speech, Prepare 3 key stories with STAR (Situation, Task, Action, and Results) Format, Study the company, know your interviewers, and 3 questions



Ex. 18-19Apr: Philadelphia **21st American Pharma and Biotech Project, Program and Portfolio Management Conference - Why Summits**

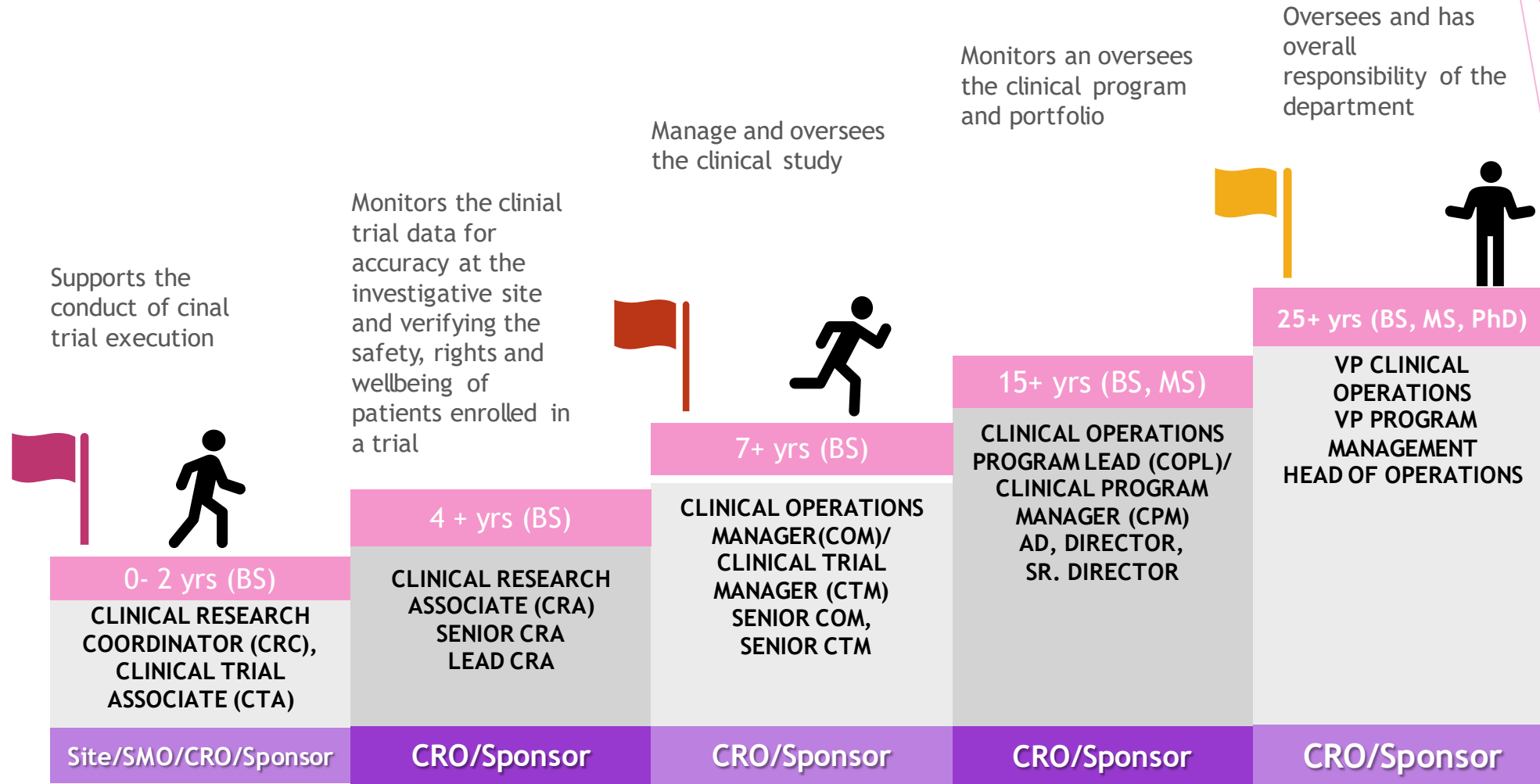
The Association of Clinical Research Professionals (ACRP): <https://www.acrpnet.org/>

Drug Information Association (DIA): <https://www.diaglobal.org/>

Society for Clinical Research Associates (SOCRA): <https://www.socra.org/>

Institute for Clinical Research (ICR) <https://icr-global.org/>

Clinical Research Paths



Site Management Organization (SMO) and Contract research organization (CROs) ~4,250 in US
 Pharmaceutical, biopharmaceutical, or device company (Sponsor)
 Clinical research vendor or technology company
 Clinical Research Study Site/ Academia or Site Network that conducts research

How 5 VPs of Clinical Operations Entered the Industry

Senior Vice President Clinical Operations

- Entry level CRA at a generics company that was recruiting from the USC career office
- BS, Biomedical Engineering
- MS, Regulatory Science



Vice President Clinical Operations

- Research Supervisor in a lab at an academic institution
- Study Coordinator in a community clinic

Vice President Clinical Operations

- Could not find a job after obtaining a master degree in Clinical Research Administration
- Worked at a medical college in an entry level role and worked their way up
- BS, Psychology
- MS, Clinical Research Administrations
- DrPH Public Health

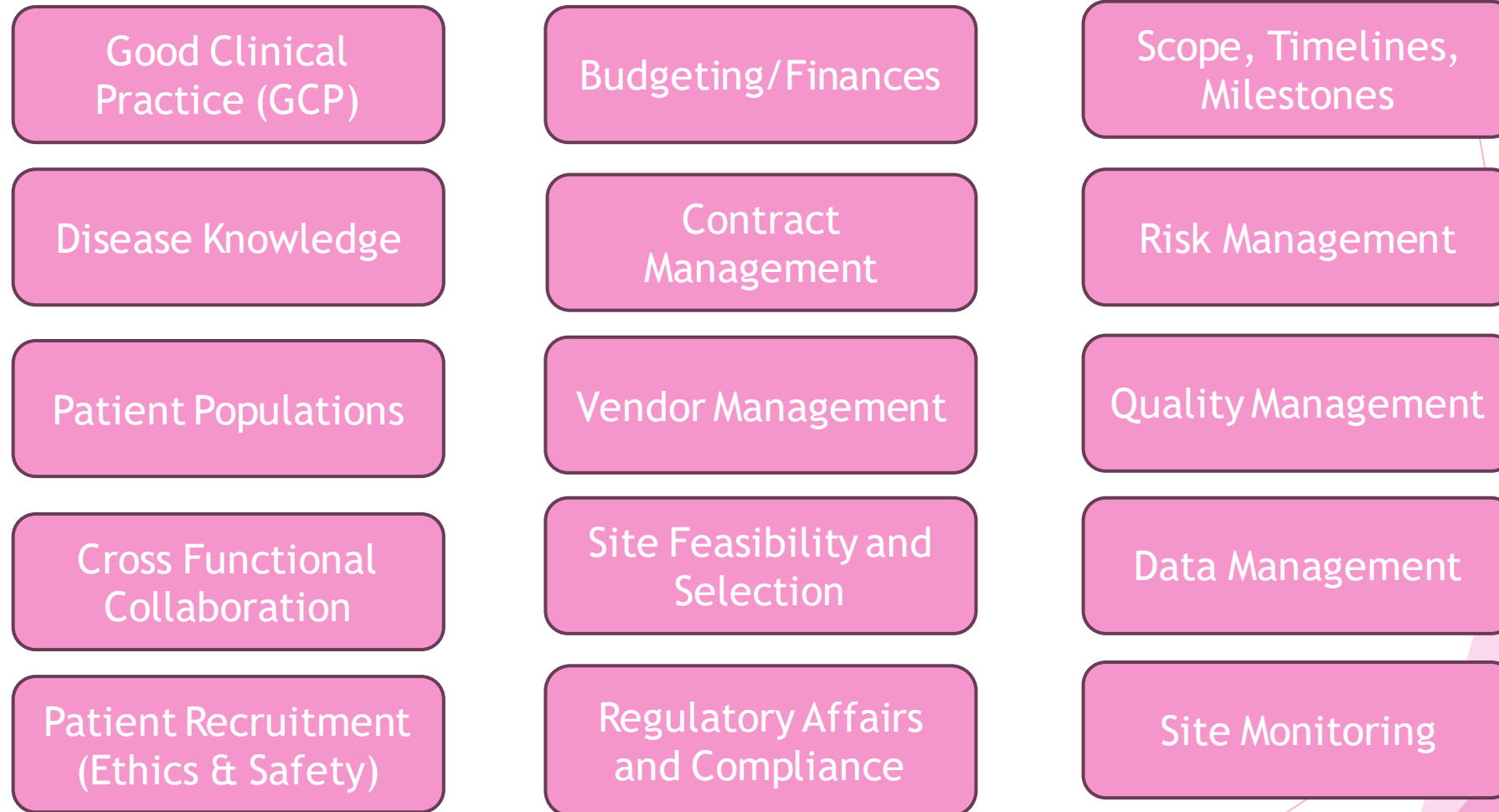
Senior Vice President Clinical Operations

- Study Coordinator at an urgent care center
- BA, Public Administration/Healthcare Management

Senior Vice President Clinical Operations

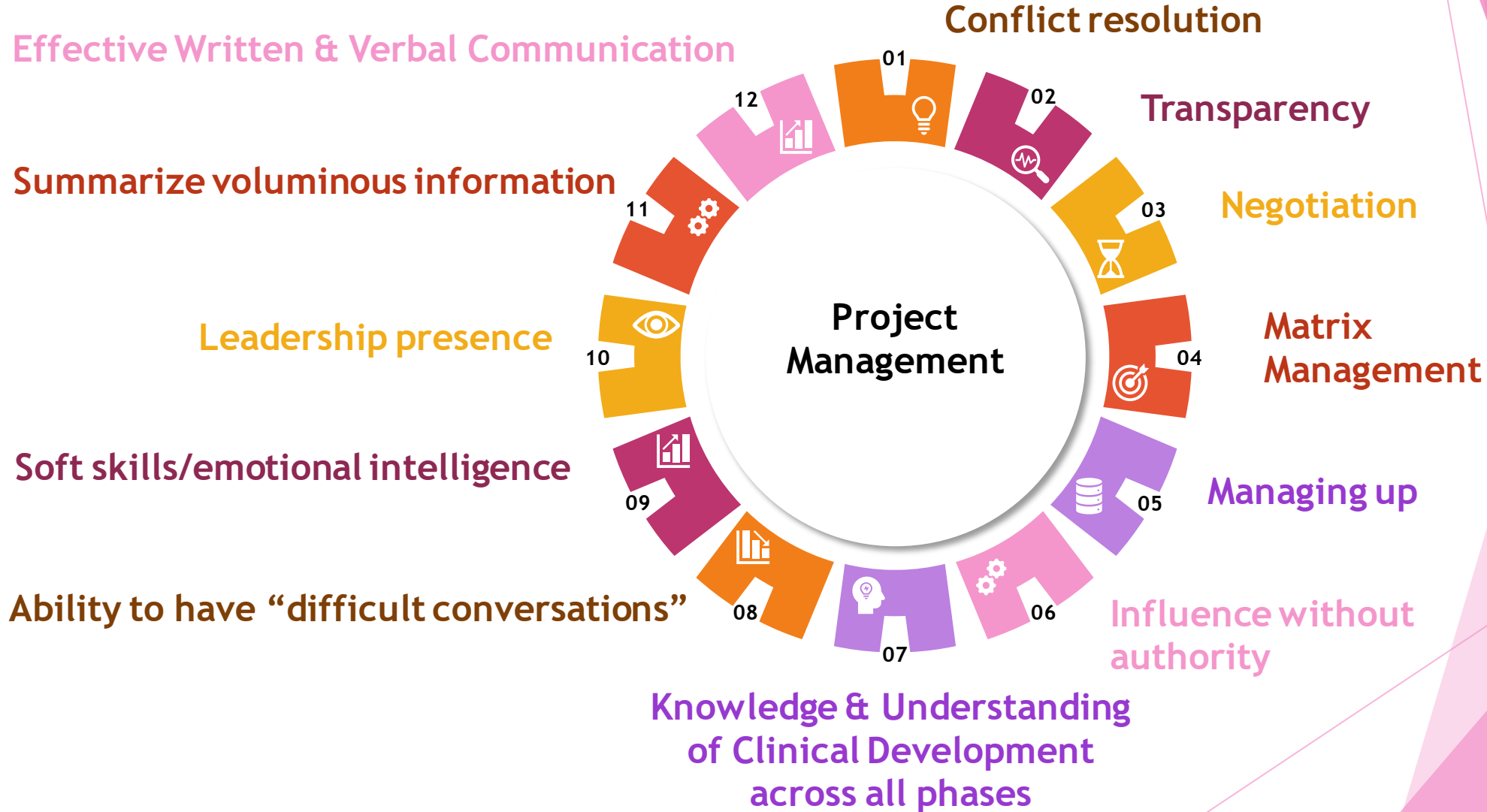
- Laboratory representative
- Tried several times to move into the R&D dept and was rejected
- Left company years later to get a CRA role
- Nursing Degree
- International Business Degree

Project Management in Clinical Research



PM ensures the successful development, approval, and commercialization of drugs while adhering to strict regulations and maintaining the highest standards of quality and safety

Critical Skills for Success= Communication



A Day in the Life of Clinical Operations Project Manager

☆ Early start and Late finish due to time zones and global programs
☆

Reading, Preparing and Responding to Emails, messages and Queries
(Timeline management, ability to prioritize and optimize processes)

Systems -Financial, Study Specific, Quality, Legal, HR, (Digital Fluency)

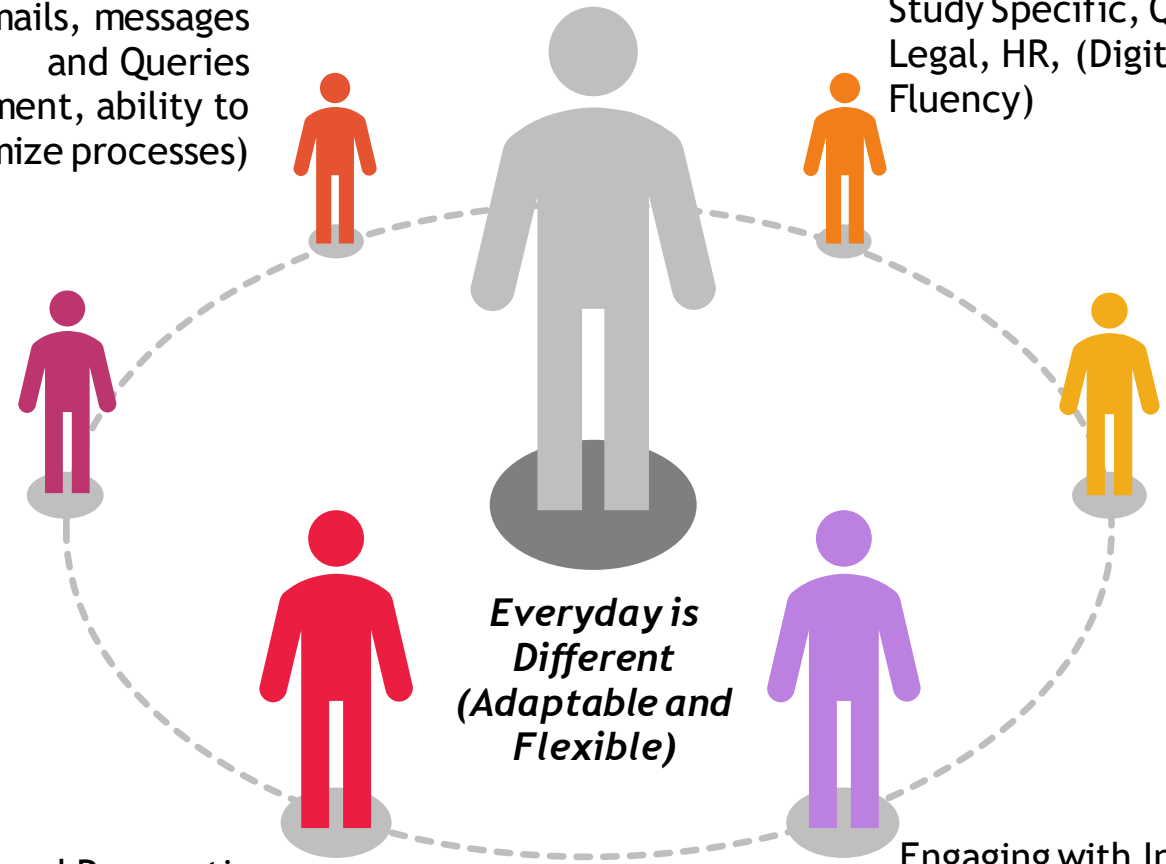
Training and Development
(Agile to work across different phases, TX areas, and global trial management)

Preparing, Executing and following up with Meetings(Facilitate mtgs, Critical thinking and problem solving, Scenario planning, ability to move from details to higher messaging for senior leaders)

*Everyday is Different
(Adaptable and Flexible)*

Document Review and Preparation
(Foundational knowledge of drug development process, SOPs, GCP and ICH Guidelines)

Engaging with Internal and External stakeholders (Sites, KOLs, Vendors, Regulatory Agencies)



Technology and Innovation Project Management Tools

