

The Impact of Project Management in Healthcare Product Development

Meeting: November 15-18 | Virtual



PROGRAM COMMITTEE

Karla Childers, MS

Bioethics & Strategic Projects Leader, Office of the Chief Medical Officer
Johnson & Johnson

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Consultant To Daiichi Sankyo, Inc.
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Executive Director, Program Team Leader
Ultragenyx Pharmaceuticals

Leigh Shultz, PhD, PMP

Head, Commercial Trade Channels
Merck & Co., Inc.

Elizabeth Somers, MS

Executive Director of Infectious Disease, Global Project and Alliance Management
Merck & Co., Inc.

Overview

DIA is proud to present a dedicated event that focuses on the integration of project/portfolio management and research and development in the healthcare setting that is objective and driven by practitioners, for practitioners. This conference is tailored for project managers in healthcare product development to provide relevant information to be successful given the current climate. Project managers working in all stages of the healthcare product lifecycle will share their perspectives on managing projects during a pandemic and utilizing lessons learned for resource planning, opportunity costs, and trade-offs. Other discussions will be centered on building resiliency in the workplace, understanding and learning from failures in drug development, and appreciating and utilizing diverse leadership styles to drive projects forward.

The Impact of Project Management in Healthcare Product Development meeting is a neutral platform for project and portfolio knowledge sharing related to healthcare research and development. This meeting will provide an in-depth contemplation of topics specific to healthcare product development and project management needs.

Who Should Attend

Professionals and students from industry, academia, and government involved in all phases of the healthcare product lifecycle who are interested in applying new skills and tools to improve program and project execution including:

- Global Project Management and Leadership
- Portfolio and Alliance Management
- Functional Leaders and team members
- Clinical Operations
- Regulatory Affairs Professionals
- Clinical Development
- CMC

Schedule At-A-Glance

Sessions held in ET

DAY ONE | MONDAY, NOVEMBER 15

10:00-10:30AM	Session 1: Keynote Address: The Value of Project Management in the Increasingly Complex Healthcare Ecosystem
10:30-10:45AM	Welcome and Opening Remarks
10:45-11:00AM	Break/Visit the Virtual Exhibit Hall
11:00AM-12:30PM	Session 2: Delivering COVID-19 Vaccines in the Midst of a Global Pandemic - a Reflection
12:30-1:30PM	Break/Visit the Virtual Exhibit Hall
1:30-3:00PM	Session 3: Development of COVID-19 Therapeutics and Diagnostics During a Global Pandemic
3:00-3:15PM	Break/Visit the Virtual Exhibit Hall
3:15-3:45PM	Session 4: Agile 101: Introduction to New Ways of Working

DAY TWO | TUESDAY, NOVEMBER 16

10:00-11:00AM	Session 5: Successful Co-Development of Oncology Programs: The Strength of a Partnership During an Unprecedented Virtual Environment
11:00-11:15AM	Break/Visit the Virtual Exhibit Hall
11:15AM-12:45PM	Session 6: The Impact of the Global Pandemic on Healthcare Project Managers
12:45-1:45PM	Break/Visit the Virtual Exhibit Hall
1:45-3:30PM	Session 7: After Action Review Workshop

DAY THREE | WEDNESDAY, NOVEMBER 17

10:00-11:00AM	Session 8: How Will Our Experience Developing COVID Vaccines Change the Landscape of Vaccine Development?
11:00-11:15AM	Break/Visit the Virtual Exhibit Hall
11:15AM-12:15PM	Session 9: You're on Mute - How to be Effective in the New Virtual World
12:15-1:15PM	Break/Visit the Virtual Exhibit Hall
1:15-2:45PM	Session 10: Valuing Diverse Leadership Styles
2:45-3:15PM	Break/Visit the Virtual Exhibit Hall
3:15-4:45PM	Session 11: Resilience - A Workshop for Leaders

DAY FOUR | THURSDAY, NOVEMBER 18

10:00-11:00AM	Session 12: Career Junctions: Transfer of Skills to New Opportunities and Environments
11:00-11:30AM	Break/Visit the Virtual Exhibit Hall
11:30-11:45AM	Closing Remarks
11:45AM-1:15PM	Session 13: How Drug Development Could Change Post-COVID

Learning Objectives

At the conclusion of this activity, participants should be able to:

- Discuss the important role that project managers play in managing complexity and enabling execution in healthcare product development
- Describe how COVID-19 changed project management for vaccine, therapeutic, and diagnostic development
- Identify methods of adaptation and lessons learned from managing projects during the COVID-19 pandemic and apply best practices as new standards for healthcare product development
- Apply methodologies and technologies to enhance project planning, learn from past experiences, and effectively lead and collaborate on projects
- Describe the adaptations and methods that project managers used during the pandemic to deliver vaccines, therapeutics, and diagnostics under stress and accelerated timelines

Continuing Education



Drug Information Association (DIA) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This conference is designated for up to 15 contact hours or 1.5 continuing education units (CEU's). Type of Activity: Knowledge.



ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, DECEMBER 31, 2021

Continuing Education Credit Allocation:

November 15, 2021 – The Impact of Project Management in Healthcare Product Development – Day 1: 4 contact hours or .4 CEUs Type of Activity: Knowledge, 0286-0000-21-045-L04-P

November 16, 2021 – The Impact of Project Management in Healthcare Product Development – Day 2: 3.5 contact hours or .35 CEUs Type of Activity: Knowledge, 0286-0000-21-046-L04-P

November 17, 2021 – The Impact of Project Management in Healthcare Product Development – Day 3: 5 contact hours or .5 CEUs Type of Activity: Knowledge, 0286-0000-21-047-L04-P

November 18, 2021 – The Impact of Project Management in Healthcare Product Development – Day 4: 2.5 contact hours or .25 CEUs Type of Activity: Knowledge, 0286-0000-21-048-L04-P

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by Friday, December 31, 2021, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.



DIA has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI). This program offers a maximum of 15 professional development unit (PDUs).

PMI # Day 1: 2166ZJH96B 4 PDUs

PMI # Day 2: 21666TUDB7 3.5 PDUs

PMI # Day 3: 21665GNXF6 5 PDUs

PMI # Day 4: 2166NH8OSO 2.5 PDUs

The PMI Registered Education Provider logo is a registered mark of the Project Management Institute, Inc.

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual conference, you must virtually attend (in their entirety) one or all four days of the conference, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Thursday, December 2, 2021**.

If you are claiming ACPE credit for this event you must:

- Attend one or both days of the live virtual conference
- Complete a Verification of Attendance Form
- Send back to **CE@DIAglobal.org** by November 25, 2021
- Access your DIA account and select My Transcript to claim your ACPE credit, available on Thursday, December 2, 2021

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It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices. All relevant financial relationships have been mitigated by DIA.

Disclosure statements are included with each speaker's biographical sketch which can be found in the Know Before You Go email.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**

10:00-10:30AM

Session 1: Keynote Address: The Value of Project Management in the Increasingly Complex Healthcare Ecosystem

Session Chair

Leigh Shultz, PhD, PMP, Head, Commercial Trade Channels, Merck & Co., Inc.

With the cost of healthcare and the long timelines for development of new products continually in the spotlight, perhaps never more so than during the COVID-19 pandemic, multiple studies have evaluated the investment required by pharmaceutical and biotech companies to bring a new product to market, with recent estimates ranging from \$300 million to \$2.8 billion. The timelines and cost are driven in part by the complexity of product development, which requires the careful integration of many disparate activities into a well-orchestrated and executable plan. A recent perspective by Wagner, et al. in *Nature Reviews Drug Discovery* noted that “in the absence of strong coordination and communication, the complex and dynamic process of drug development frequently fails.” Project Managers in this ecosystem play an increasingly important role in bringing new therapies to patients as quickly as possible and minimizing failure.

Learning Objectives

- Explain some of the recent dynamics driving the continued increase in complexity, cost, and timelines in product development
- Discuss the value of integrated planning and careful management of execution
- Discuss the important role that project managers play in managing complexity and enabling execution

Speaker

Sandra Milligan, MD, JD, Head of Research and Development, Organon & Co

10:30-10:45AM

Welcome and Opening Remarks**Speakers**

Mark Kryah, PMP, Executive Director, Program Team Leader, Ultragenyx Pharmaceuticals

Tamei Elliott, Manager, Scientific Programs, DIA

10:45-11:00AM

Break/Visit the Virtual Exhibit Hall

11:00AM-12:30PM

Session 2: Delivering COVID-19 Vaccines in the Midst of a Global Pandemic – a Reflection

Session Chair

Karla Childers, MS, Bioethics & Strategic Projects Leader, Office of the Chief Medical Officer, Johnson & Johnson

In this session, we will reflect on the pandemic and the fast-paced development of authorized COVID-19 vaccines. Representatives will share their experience about what it was like to move these critical programs forward under intense time pressure and scrutiny.

Learning Objectives

- Explain the unique experiences of vaccine developers during a global pandemic and the interplay of the public/private partnership
- Discuss how project teams worked under intense scrutiny and with a high degree of stress and time pressure to successfully deliver vaccine candidates
- Describe the challenge of working both within and outside of various multistakeholder arrangements

Speakers

Matt Clark, PhD, PMP, Former Lead Program Manager, Vaccine Development, Operation Warp Speed, US Department of Health and Human Services (HHS) and US Army

Mark Boaz PhD, PMP, Senior Director, Pfizer Vaccines Research and Development, Pfizer Inc

12:30-1:30PM	Break/Visit the Virtual Exhibit Hall
1:30-3:00PM	<p>Session 3: Development of COVID-19 Therapeutics and Diagnostics During a Global Pandemic</p> <p>Session Chairs</p> <p>Nita Ichhpurani, PMP, Consultant To Daiichi Sankyo, Inc. Phase One Forward, Consultant, Canada</p> <p>Elizabeth Somers, MS, Executive Director of Infectious Disease, Global Project and Alliance Management, Merck & Co., Inc.</p> <p>In this session, we will share case studies of COVID-19 therapeutic and diagnostic development in response to the global pandemic. Through these case studies we will be able to evaluate the utilization of project management skillsets. We will explore the need to focus teams and product development strategy to enable execution amidst an evolving landscape.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"> • Compare and contrast the development of therapeutics before and during a global pandemic • Compare and contrast the development of diagnostics before and during a global pandemic • Explain how project teams worked under intense scrutiny and with a high degree of stress and time pressure to successfully deliver products <p>Speakers</p> <p>Kristi Huntington, MS, Senior Advisor, Pharma Project Management - Eli Lilly and Company</p> <p>LTC John Nuckols, Joint Product Manager at Joint Product Executive Office for Chemical, Biological, Radiological and Nuclear Defense</p> <p>Erik Mogalian, Vice President, Program Executive, COVID, Vir Biotechnology, Inc.</p>
3:00-3:15PM	Break/Visit the Virtual Exhibit Hall
3:15-3:45PM	<p>Session 4: Agile 101: Introduction to New Ways of Working</p> <p>Session Chair</p> <p>Leigh Shultz, PhD, PMP, Head, Commercial Trade Channels, Merck & Co., Inc.</p> <p>The rise of digital, combined with increasing data and analytics capabilities, has been transforming the healthcare industry in recent years. This transformation has been accelerated by the COVID-19 pandemic. To be successful in the “next normal” companies are adopting flexible, agile operating models that allow for rapid response to patient and customer needs, and the ability to quickly innovate, test and learn. This session provides an overview of agile ways of working for those with little to no previous exposure to this methodology.</p> <p>Learning Objectives</p> <ul style="list-style-type: none"> • Define agile • Explain how the agile methodology works and what differentiates it from traditional planning approaches • Discuss potential applications and the benefits of agile in planning and executing projects <p>Speaker</p> <p>Laura Pittman, MS, MBA, Associate Partner, McKinsey & Company</p>
DAY TWO TUESDAY, NOVEMBER 16	
10:00-11:00AM	<p>Session 5: Successful Co-Development of Oncology Programs: The Strength of a Partnership During an Unprecedented Virtual Environment</p> <p>Session Chair</p> <p>Nita Ichhpurani, PMP, Consultant To Daiichi Sankyo, Inc., Phase One Forward, Consultant, Canada</p>

This presentation will focus on the critical role of Project Management in establishing and growing a collaboration between two diverse companies to deliver novel treatments to cancer patients. We will share the story of how these two companies united in 2019 and continue to evolve their ways of working to translate a bold ambition into an executable plan. Direction for this partnership required Project Management to determine an efficient path forward throughout the project life cycle by translating strategy into executable plans, providing clarity on alignment and decision-making processes, influencing leaders and motivating and energizing teams. The success of the first partnered project was pivotal to the establishment of a second collaboration between the companies.

Learning Objectives

- Describe project management elements of a “high touch” collaboration
- Demonstrate how to structure “ways of working” to deliver clarity, speed, and efficiency
- Discuss the role of Project Managers in leading with empathy

Speakers

Priya Kannan, PhD, MS, Head, Business Planning and Operations, Late Stage Oncology, Astra Zeneca

Radha Ramkumar, PhD, MBA, Executive Director, Daiichi Sankyo Co., Ltd.

Koji Ishizuka, MSc, MBA, MBA, MS, Alliance Director, Oncology Alliance Management, Daiichi Sankyo, Inc

11:00-11:15AM

Break/Visit the Virtual Exhibit Hall

11:15AM-12:45PM

Session 6: The Impact of the Global Pandemic on Healthcare Project Managers

Session Chair

Karla Childers, MS, Bioethics & Strategic Projects Leader, Office of the Chief Medical Officer, Johnson & Johnson

In this session, we will explore how healthcare PMs and their teams tackled the challenges brought about by the pandemic to non-COVID projects. While a great deal of attention has been paid to the impact of COVID-19, the need to continue to deliver life saving medicines, medical devices, and healthcare services, in general, did not go away.

Learning Objectives

- Identify key lessons from the experiences of PMs who had to pivot and evolve their projects as a result of the pandemic
- Explain how the ability to adapt and pivot can be applied beyond global public health emergencies
- Apply these concepts to their own projects

Speakers

Jeremy Baker, MBA, PMP, Pharma Project Management, Eli Lilly & Co

Gina Marie Chevalier, MS, Senior Manager Strategic Projects, Office of the Chief Medical Officer, Johnson & Johnson

12:45-1:45PM

Break/Visit the Virtual Exhibit Hall

1:45-3:30PM

Session 7: After Action Review Workshop

Session Chair

Mark Kryah, PMP, Executive Director, Program Team Leader, Ultradex Pharmaceuticals

Operating in a pandemic has offered the rare opportunity to learn so much in a short time. Good or bad, we should examine our successes and failures, and institutionalize those best practices that have made us all better at our work and personal lives. After Action Reviews (AARs) provide a structure to leverage these learnings. This interactive session will provide some fundamentals for conducting AARs, a case study for small groups to discuss in breakout rooms, and a debrief as a large group.

Learning Objectives

- Explain the process for conducting AARs
- Discuss the key aspects of AARs based on a case study
- Create an AAR based on a past experience

Speakers

Mark Kryah, PMP, Executive Director, Program Team Leader, Ultragenyx Pharmaceuticals

Colonel Victor Suarez MS, CMRP, Vaccine Program Manager, HHS/BARDA/DOD

DAY THREE | WEDNESDAY, NOVEMBER 17

10:00-11:00AM

Session 8: How Will Our Experience Developing COVID Vaccines Change the Landscape of Vaccine Development?

Session Co-Chair

Nita Ichhpurani, PMP, Consultant to Daiichi Sankyo, Inc., Phase One Forward, Consultant, Canada

Matt Lawlor, Executive Director and Interim Lead, Global Program Management, NOVAVAX INC

COVID-19 vaccine development has propelled our industry to operate and collaborate in an unprecedented manner. What can we apply to future projects from Project Managers who have navigated in this global public health crisis? This session will focus on the lessons learnt, best practices and ways of working which can be taken forward as a result of the urgent planning and management required. We will discuss the successes, challenges and complications experienced which can inform future management of vaccine development.

Learning Objectives

- Discuss best practices to utilize moving forward in vaccine development
- Identify PM tools and skills which were most useful to vaccine development
- Apply lessons learned to future vaccine projects

Speakers

Matt Lawlor, Executive Director and Interim Lead, Global Program Management, NOVAVAX INC

Heather Lawlor MS, PMP, Associate Director, Global Portfolio and Project Management at AstraZeneca

11:00-11:15AM

Break/Visit the Virtual Exhibit Hall

11:15AM-12:15PM

Session 9: You're on Mute – How to be Effective in the New Virtual World

Session Chair

Karla Childers, MS, Bioethics & Strategic Projects Leader, Office of the Chief Medical Officer, Johnson & Johnson

The public health emergency has had significant impact on how we interact with one another and get work done. We've all learned about the pitfalls of inadvertent video bombs, misadjusted cameras, and have heard "you're on mute" enough that we should all have it printed on t-shirts at this point. This session will review some of the best practices we've accumulated during this virtual period and help PMs choose these tools more effectively as they continue to evolve and adapt in what we envision is a forever changed, hybrid world.

Learning Objectives

- Identify the right virtual interaction model for a given purpose – also known as "we don't have to zoom all the time"
- Identify soft skills and best practices for running meetings on virtual platforms
- Discuss options and best practices for integrating collaborative and meeting tools

Speakers

Karla Childers, MS, Bioethics & Strategic Projects Leader, Office of the Chief Medical Officer, Johnson & Johnson

Leigh Shultz, PhD, PMP, Head, Commercial Trade Channels, Merck & Co., Inc.

Sue Glaskey, MA, PMP, Executive Program Director, Project Management Leadership Group

12:15-1:15PM

Break/Visit the Virtual Exhibit Hall

1:15-2:45PM

Session 10: Valuing Diverse Leadership Styles

Session Chair

Elizabeth Somers, MS, Executive Director of Infectious Disease, Global Project and Alliance Management, Merck & Co., Inc.

Session Description: Research has shown that authentic leaders are effective and build strong teams. Even with the transparency around the value of diverse leadership styles, assumptions can be made regarding how impactful an individual may be based on their personal style. For example, a team may assume an extroverted, directive leader will be stronger than an introverted, collaborative leader. During this session, we will hear from leaders with diverse styles to gain insight into building an inclusive team environment that leverages personal strengths and backgrounds.

Learning Objectives

- Explain the value of diverse leadership styles
- Employ tools to challenge assumptions and confront unconscious bias
- Identify their personal leadership style

Speakers

Farhana Pruthi, MS, PMP, Bristol Myers-Squibb, Associate Director, Program Management

Doug Carney, MBA, Business Development Manager, Northrop Grumman Corporation

Christine Garrett, PhD, PMP, Vice President, Head of Late Development Project Management, Bristol-Meyers Squibb

2:45-3:15PM

Break/Visit the Virtual Exhibit Hall

3:15-4:45PM

Session 11: Resilience – A Workshop for Leaders

Session Chair

Leigh Shultz, PhD, PMP, Head, Commercial Trade Channels, Merck & Co., Inc.

Resilience has always been considered a key enabler for successful leaders, but the disruption and stress associated with the COVID-19 pandemic has highlighted its importance as a critical skill for everyone, at home and at work. In this hands-on session, we will review what resilience is (and what it isn't), why it is important, and work through practical ways to improve your resilience and that of your team.

Learning Objectives

- Define Resilience
- Understand the importance of resilience as a key leadership skill
- Apply 1-3 tools/techniques discussed to build the resilience of themselves and others

Speakers

Matt Clark, PhD, PMP, Former Lead Program Manager, Vaccine Development, Operation Warp Speed, US Department of Health and Human Services (HHS) and US Army

Leigh Shultz, PhD, PMP, Head, Commercial Trade Channels, Merck & Co., Inc.

DAY FOUR | THURSDAY, NOVEMBER 18

10:00-11:00AM

Session 12: Career Junctions: Transfer of Skills to New Opportunities and Environments

Session Chair

Elizabeth Somers, MS, Executive Director of Infectious Disease, Global Project and Alliance Management, Merck & Co., Inc.

The workplace of the future will look different than it has in the past and vary from what it looks today due to the normalization of working remotely. Across the healthcare industry, employees have pivoted to working in completely virtual teams. From a career development perspective, it can be challenging to take steps into a new role or new company when working remotely is the norm rather than the exception. When considering a new opportunity, a candidate assesses the culture of the organization as well as the job role. In situations where a candidate is looking to move into a different type of role, this assessment and the feasibility of transferring their skills becomes even more important. During this panel session we will hear from individuals who have identified opportunities, transferred their skills and learned how to integrate into a new organization working virtually.

Learning Objectives

- Identify key considerations when assessing opportunities remotely
- Identify foundational skills that can be transferred to new roles or new organizations regardless of working environment
- Discuss beneficial adjustments in skillsets that can enable stronger integration into virtual teams and organizations

Speakers

Dara Meyer, MS, PMP, Senior Project Manager, Icahn School of Medicine, Mount Sinai Clinical Intelligence Center

Andrea Vresilovic, Director Clinical Development and Program Management, NexEos Bio

11:00-11:30AM

Break/Visit the Virtual Exhibit Hall

11:30-11:45AM

Closing Remarks

11:45AM-1:15PM

Session 13: How Drug Development Could Change Post-COVID

Session Chair

Mark Kryah, PMP, Executive Director, Program Team Leader, Ultragenyx Pharmaceuticals

The COVID-19 pandemic forced everyone to think and work differently. The good news is that many changes, independent of COVID, should become new standards for the way drug development is planned and executed. This panel session will discuss some of the areas that may become future paradigms for drug development.

Learning Objectives

- Describe how COVID-19 changed existing drug development practices
- Identify areas of change within your environment
- Apply these changes as new standards for drug development

Speakers

Mark Kryah, PMP, Executive Director, Program Team Leader, Ultragenyx Pharmaceuticals

Athena Papas, DMD, PhD, Distinguished Professor Diagnostic Sciences, Tufts School of Dental Medicine

Teresa Lamantia, MSN, RN, Senior Vice President, Operational Transformation & Performance, IQVIA

Dawn Hawkins, Manager, Pharmaceutical Project Management, Eli Lilly and Company