DIA LEARNING

Agenda for Artificial Intelligence (AI) Courses

DIA LEARNING

IMPLEMENT CONSULTING GROUP_

Transforming Regulatory Affairs with Generative AI: Practical Integration for Smarter, Faster Outcomes

Agenda

April 21, 2026 9:00 AM – 1:00 PM EST / 2:00 PM – 6:00 PM CET

9:00-9:20 AM Introduction & Purpose

- Introduction
- Purpose and expectations for the day

9:20-10:05 AM Session 1: Introduction to Generative AI in a Regulatory Setting

- Introduction to technology and potentials: expected productivity & quality gains
- Pitfalls, limitations and biases to be aware of when working with GenAI
- Specific considerations when using GenAI in a Regulatory setting including dos and don'ts
- Examples of practical application in Regulatory such as health authority interaction, quality check of e.g. SmPC and SPL and CCDS translation support

10:05-10:15 AM Break

10:15 AM -12:00 PM Session 2: Practical Applications

(There will be a 10-minute break halfway through this agenda point)

- Introduction to prompt engineering and prompting strategies
  - How to create good prompts that ensure reliable, high-quality outputs
  - How to work with structured data and documents like eCTD, SmPC, SPL, labelling and more
  - Generative AI in a Regulatory setting, based on real life use cases, exemplifying use, to inspire application in own daily work
- Guided hands-on work for participants: Overview of Regulatory practical applications and use cases, own work with examples based on standard and accessible GPT-based tools

12:00-12:10 PM Break

12:10-1:00 PM Session 3: Engagement and Reflection

- Individual work on regulatory case
  - Participants can use their own cases or choose from ones shared by instructors
- Reflections (e.g., process v. result, when to use and not to use GenAI for work)
- Making GenAI a habit in daily work and finding ideas of use
- Reflections and commitments on own work, such as, "What will you do differently, starting tomorrow?"

DIA LEARNING

IMPLEMENT CONSULTING GROUP_

Transforming Clinical Development with Generative AI: Practical Integration for Smarter, Faster Outcomes

Agenda

April 23, 2026 9:00 AM – 1:00 PM EST / 2:00 PM – 6:00 PM CET

9:00-9:20 AM Introduction & Purpose of today

- Introduction of instructors and participants
- Purpose and expectations for the day

9:20-10:05 AM Session 1: Introduction to Generative AI in a Clinical Setting

- Introduction to technology and potentials: expected productivity & quality gains
- Pitfalls, limitations and biases to be aware of when working with GenAI
- Specific considerations when using GenAI in a Clinical setting including dos and don'ts
- Examples of practical application in Clinical such as evaluation of participant inclusion/exclusion criteria, optimizing trial by testing scenarios and budget and risk planning

10:05-10:15 AM 10-minute break

10:15 AM-12:00 PM Session 2: Practical Applications

(There will be a 10-minute break halfway through this agenda point)

- Introduction to prompt engineering and prompting strategies
  - How to create good prompts that ensure reliable, high-quality outputs
  - How to work with structured data and documents like Clinical Trial Protocols, Investigator Brochures and more
  - Generative AI in a Clinical setting, based on real life use cases, exemplifying use, to inspire application in own daily work
- Guided hands-on work for participants: Overview of Clinical practical applications and use cases, own work with examples based on standard and accessible GPT-based tools

12:00-12:10 PM 10-minute break

12:10-1:00 PM Session 3: Engagement and Reflections

- Individual work on clinical case
  - Participants can use own cases or choose from ones shared by instructors
- Reflections (e.g., process vs. result, when to use and not to use GenAI for work)
- Making GenAI a habit in daily work and finding ideas of use
- Reflections and commitments on own work, such as, "What will you do differently, starting tomorrow?"

Integrating AI into Medical Affairs Workflows for Efficiency and Impact

Agenda

April 29, 2026 10:00 AM – 2:00 PM EST / 3:00 PM – 7:00 PM CET

10:00-10:10 AM	Opening and Objectives • Introduction • Purpose and expectations for the day
10:10-10:50 AM	When to Use AI: The Four Superpowers of AI
10:50-11:00 AM	Break
11:00-11:50 AM	Prompting for Efficiency and Impact
11:50 AM -12:00 PM	Break
12:00-12:50 PM	AI Alphabet Soup (Agents, CustomGPTs, and More)
12:50-1:00 PM	Break
1:00-2:00 PM	Future of AI in Medical Affairs: What's Coming in 2026

DAY 1

15:00 WELCOME AND INTRODUCTION

15:30 SESSION 1

PV JOURNEY FROM MANUAL THROUGH ROBOTIC PROCESS AUTOMATION (RPA) TO AI

Jan Petracek

- Business experience from 10-year-long journey of implementation of intelligent automation in pharmacovigilance
- Areas of immediate and near future impact of AI technologies, ethical and legal considerations
- What is changing in pharmacovigilance and why, the main trends and competencies needed for the near future
- AI initiatives from major regulatory authorities and CIOMS

17:00 BREAK

17:30 SESSION 2

AI FUNDAMENTALS FOR PV

Andrew Mitchell

- Background and Introduction
- Adoption of AI in Pharmacovigilance
- Use Cases & Classifications
- Critical AI Techniques, including
  - Supervised vs Unsupervised vs Transfer Learning
  - Prompt Engineering
  - RAG Architectures
  - Small Language Models

19:00 DISCUSSION AND Q&A

19:30 END OF DAY 1

DAY 2

15:00 SESSION 3

COMPLIANCE AND MANAGEMENT PERSPECTIVE ON IMPLEMENTING INTELLIGENT AUTOMATION

Jan Petracek

- Business case and management views - how senior management and CEOs view investments in innovative technology
- Prepare your departments, teams, hire the right talent, and create your roadmaps
- What are some of the myths on either side - management and business and how might we bridge them
- Exercise a clever approach to validation and quality management requirements to stay compliant while using the most modern technology
- Defense of more intelligent data management practices in front of auditors and inspectors

16:30 BREAK

17:00 SESSION 4

TODAY'S PV INTERFACES AND SYSTEMS

Andrew Mitchell

- PV Systems: Vendor Landscape, Observations and Predictions
- AI in PV – Use Cases
- Deploying AI for Pharmacovigilance
- How Are Regulators Responding to AI in PV?
- Human-in/on-the-Loop (HITL/HOTL)
- Key Principles to Adoption
- Validation Categories for GxP AI Systems
- Community Resources

18:30 DISCUSSION AND Q&A

19:30 END OF DAY 2

DAY 3

15:00 SESSION 5

NEAR FUTURE PV IT DEVELOPMENTS

Andrew Mitchell

- Rapid Shift from ML/NLP to GenAI
- Transforming PV for Agentic AI
  - Organization Change
  - Infrastructure
  - Data
  - Business Transformation
- Learning from a Risk-Based Approach

16:30 BREAK

17:00 SESSION 6

DEVELOPING REGULATORY ENVIRONMENT FOR AI IN PV

Jan Petracek, Andrew Mitchell and Phil Tregunno

- Case studies
- View of leading regulators
- Discussion and Q&A

18:00 SESSION 7

STEP BY STEP AI IMPLEMENTATION

Jan Petracek

- Overview of all steps in pharmacovigilance and how to boost productivity and quality in each of them using various AI tools
- Case studies demonstrating strengths and weaknesses
- Developing roadmap of AI implementation for your PV department
- Q&A

19:30 END OF THE VIRTUAL LIVE TRAINING COURSE