

ITEN[®]

LEVEL UP

YOUR LEARNING, LEADERSHIP & IMPACT



Ensuring a Successful Launch with Intentional Medical Affairs Training
Across the Launch Continuum



READY PLAYER 1



SHARE YOUR FEEDBACK ON TODAY'S SESSION

CHOOSE THIS WORKSHOP

IN THE APP... EASY!

CLICK ON THE SURVEY

AND ANSWER A FEW QUICK QUESTIONS.



LTEN[®]



LEVEL UP

YOUR LEARNING, LEADERSHIP & IMPACT



READY PLAYER 1





WELCOME



JENNIFER AIKIN, MSN

Principal, Owner and Consultant
Evergreen Training Solutions, LLC

- Trained as an Oncology APN
- 20+ years Medical Training experience in the biopharma industry
- Also worked as an MSL and Head of Enterprise-wide Training



CHRISTIE SPADAFORA, MS, MBA

Director, NeuroPsychiatry Medical Affairs Training
and Development
Karuna Therapeutics – A Bristol Myers Squibb Co

- Trained as a laboratory scientist
- 14 years in biotech/pharma,
11 years of training/teaching experience,
7 years of medical affairs experience
- Also worked as a Biology teacher/professor
and pharma sales rep

Introducing the Audience



LEARNING OBJECTIVES

Following this workshop, attendees will be able to:



Outline the needs assessment, information, and collaborations required to develop a Medical launch training program



Identify the components of a successful Medical launch training program



Develop a timeline containing the tactics to support a successful Medical launch training program

AGENDA

1 How to identify the key information and collaborations needed for a successful launch training program

2 How to conduct a brief, targeted needs assessment

3 Tips for creating an impactful launch training program

4 Table Group Activity

5 Summary and Conclusions

LEVEL UP



How to identify the key information
and collaborations needed for
an impactful launch training program

The Key Information You Need Up Front

Key business priorities



Medical Launch Plan / Playbooks



Commercial Launch Plan



Draft USPI



- Get the USPI as early as possible
- Ensure you get updated versions as they are developed
- Look at other relevant USPIs for potentially applicable class warnings /labelings and competitor comparisons

Other Supporting Documents



- Protocols
- Publications (manuscripts, posters, Congress presentations)

Important Collaborations

 Medical Director / SMEs

 Field Medical Lead(s)

 Pre-clinical colleagues
(PK, animal data)

 Clinical colleagues
(phase 1-3 data)

 Commercial Training

 Launch Team

 Launch POA Planning
Team

 MLR/MRC Reviewers
and Coordinator

 Legal

 Regulatory

Other Important Collaborations



Manufacturing:

sample / starter pack
information, container size,
how and where the product
will be available



Other Key Partners may include:

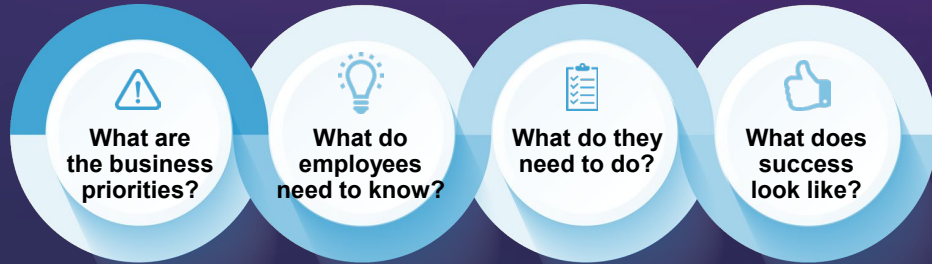
- Patient services
- Medical call center
- Value / Access team
- Diagnostic testing experts

LEVEL UP

How to conduct a Brief,
Targeted Needs Assessment

Needs Analysis: Seven Strategic Questions

Four Questions Focusing on Business Priorities



Three Questions Focusing on the Organization



Compile Results

TRAINING PLAN

LEVEL UP

Tips for creating an impactful
launch training program

Before the Label is Available (Pre-PDUFA)

Build Your Plan Early (based on your training needs assessment)

- Depending on the PDUFA date, you will have 6-12 months to execute your plan
- Timing: what can be done pre-PDUFA date? On the PDUFA date? Post-PDUFA date?
- Plan to train on anything that you anticipate will be in the label, that is not confidential, *before* the PDUFA date
- Start socializing the plan early and get buy in from key stakeholders / collaborators

Refresher Training Topics

- Disease Background for the indication
- MOA and Pre-clinical Data
- Available Clinical Data
- Competitor Landscape
 - What are the key competitors?
 - Train on MOA, administration, clinical data
 - How will your new product be differentiated from the competitors

Training Methods

- Self Study: readings, videos, podcasts, quizzes (e.g., Q-Stream)
- Interactive: live virtual training, breakouts, workshops

When the 'Final' Label is Available

Provide the Context

- Invite Regulatory to speak to the team to 'tell the story' of the label
- When did discussions with the FDA occur?
- What were points of negotiation?
- What does Regulatory think is challenging or confusing about the final label?

Walk Through the Label

- What are the key points to emphasize related to safety and efficacy of the product?
- Where does the data in the label differ from the clinical trial data?

Determine How to Document MSL Knowledge and Understanding

Options Include:

- Label Knowledge Check (documented in the LMS)
- Certification Experience (real life scenarios based on the label, or use of approved slide deck)

LEVEL UP

Table Group
Activity

Activity: Launch Case Study Worksheet

Instructions – You have 20 min

1. Each table has a worksheet outlining a launch case study
2. As a group, read the case study and fill out the worksheet together
3. Choose a spokesperson

Debrief



LEVEL UP

Final Q&A and Wrap Up