

*Webinar:*

# Regulatory Compliance and Contract Management for Emerging Life Sciences Companies



# **Challenges in Regulatory Compliance and Contract Management**

**How Emerging Life Sciences Companies  
Address these Challenges**

# Thank You for Joining us Today

Model N

**Vikram Rao**

*Director  
Global Customer  
Success*



 **TOLMAR**

**Maria Mangler**

*Director  
Contracts, Pricing  
and Reimbursement*





**Ralph Lynn**

*Vice President  
Pricing, Contracting  
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# My Experience

## Before TOLMAR

- Large then small pharmas
- Pricing and Reimbursement
- Responsible for selecting and implementing Revenue Management



## One of the very first employees at TOLMAR

- Quick history of the company
- Starting to market an already in-market product  Eligard®
- Specialty injectable; Buy and Bill; contracting with GPOs and clinics



# Midmarket vs. Big Pharma



## Typically complex therapies, different distribution

- More high touch with prescriber
- Specialty distributors, Buy & Bill, etc.
- Importance of managed care can vary a lot

## Lean organizations that need to move fast

- Need more bang for their buck while supporting fast growth
- Streamline and automate to compete with larger companies
- Need to be “compatible” to be attractive to acquirers and licensees



# Regulatory Compliance and Contract Management



## “Must Do”, like in large pharma

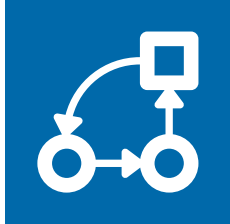
- Government reporting and pricing requirements
- Contracting obligations and expectations

## Beyond operations, value in business data collected

- We do not have another data warehouse!
- Very useful to Finance, Business Analytics, Marketing, Sales, and even C-level



# What To Do About It – Process



## Business Case

- It's part of starting a company!



## Team

- CEO must designate someone for this imperative
- Make sure all different functions have their responsibilities and goals assigned



## Change Management



# What To Do About It – Systems



**You have limited dollars but you still have to tell a story – find the most efficient way to do it**

- Need a solution that is controllable, helps drive business
- Need a solution that is scalable and flexible

**Don't be afraid to take this in-house!**

- Be in the driver's seat, understand what is going on
- Start with quick and small but robust foundation, then scale
- Good investment, saves you much time in the future





# It Does Not Have to be Long and Expensive



## Best practices derived from two decades of Revenue Management experience in the industry

- Accelerate implementation with pre-configurations, SOPs already in place
- Accelerate implementation with the cloud (ongoing maintenance and support simpler too)

**Pre-configured means best practices, not inflexible**



# How to Choose the Right Solution for You



**Depends on product / people experience**

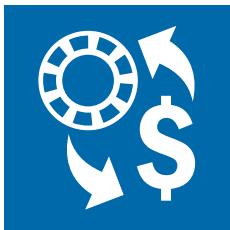


**Prioritize ease of use**

- Ability to drill down in the data, do checks and balances
- Have stakeholders come and look at the demos!



**Emphasize partnership with vendor**



**Favor quick time-to-value and high predictability of cost**



# Lean Accelerator Driven Startup Approach



## Readiness Checklist

- ✓ Master Data Quality Jumpstart
- ✓ Government Pricing Policy Review
- ✓ Integration Scope / Readiness Review
- ✓ Conversion / Cutover Readiness



## Implementation Accelerators

- ✓ Project Plan Accelerators
- ✓ Contact / Rebate Strategy Tools
- ✓ SOP / Work Instruction Driven Training
- ✓ GP Price Models / Testing Tool
- ✓ Change Management

**Implementation Advisory Team**

# Readiness / Jumpstart Checklist



***Recommended activities prior to the start of an accelerated SaaS implementation to achieve readiness and proper planning...***  
***Objective: Gain alignment from stakeholders on long duration tasks***

Accelerators	Best Practice
<b>Master Data Quality Jumpstart</b>	<ul style="list-style-type: none"><li>• Targeted review of customer, product, and class of trade utilizing data assessment workbook</li><li>• Provide dashboards to clients to begin execution and tracking remediation</li></ul>
<b>Government Pricing Policy Review</b>	<ul style="list-style-type: none"><li>• Review of GP policies</li><li>• Identify major implementation gaps</li></ul>
<b>Integration Scope / Readiness Review</b>	<ul style="list-style-type: none"><li>• Integration scoping of all inbound/outbound data</li><li>• Ensure SaaS solution can provide and consume all appropriate data</li><li>• Middleware Tools to support integration</li></ul>
<b>Conversion / Cutover Readiness</b>	<ul style="list-style-type: none"><li>• Identify scope and inventory of conversion objects</li><li>• Provide recommendations on data conversion and cutover allowing</li></ul>

# Implementation Accelerators



*Recommended activities and accelerators to reduce risk during a SaaS implementation*

*Objective: Look to Leverage Value Add Services from the Experts*

Accelerators	Best Practice
<b>Project Plan Accelerators</b>	<ul style="list-style-type: none"><li>• Pre-populated MS project plan</li><li>• Tailored to a midmarket implementation including external and internal resource assignments.</li></ul>
<b>Contract / Rebate Strategy Tools</b>	<ul style="list-style-type: none"><li>• Contract pricing and rebate templates</li><li>• Industry driven strategy approach</li><li>• Tailored to midmarket implementation to support Specialty and Managed Care scenarios</li></ul>
<b>GP Price Models / Testing Tool</b>	<ul style="list-style-type: none"><li>• Database driven Excel testing models</li><li>• Early Signoff post requirements phase</li></ul>
<b>Change Management</b>	<ul style="list-style-type: none"><li>• Targeted training classes focused on complex areas of application with the goal of becoming “self serve”</li><li>• Wholesaler communication templates, plan for EDI changes / testing / go live</li></ul>

# Summary

- **Must-Dos!**
- **Cost and time-efficient ways to do it**
- **Supports fast growth, facilitates M&A**
- **Significant added value to many in the organization**



Questions?



# Questions? Please contact us!

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# Thank You!

