ALMAC

Supply With Care™

Supply Chain Synergy: Packaging & Labeling Strategies for Global Trials

Dana Berger
Project Services Liaison

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Clinical Supply Manager

Ground Rules

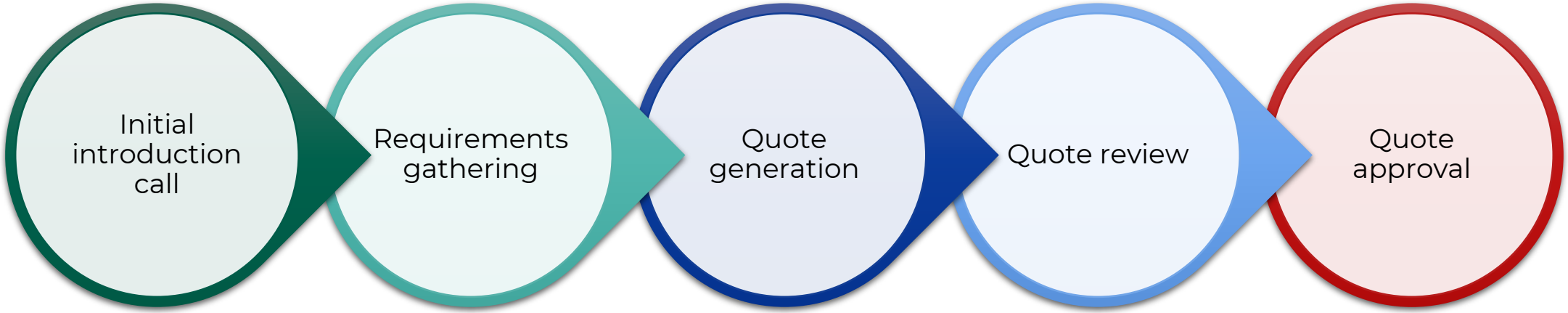
- Breaks
- Slido
- Case Studies
- Discussion

• Role of the Project Services Liaison (PSL) – Quote Scope Phase

- Partner with Business Development to build the scope of work and technical requirements for a project
- Represent the Almac Project Services department at the initiation of the client partnership
- Draft an initial project plan
- Set expectations on project deliverables
- Educate new clients on Almac processes, documentation, tools & resources; “Almac 101”

ALMAC

Request for Proposal (RFP) → Quote Award



Project Services Liaison (PSL)

• Role of the Clinical Supply Manager (CSM) – Quote Execution Phase

- Execute and oversee the scope of work and technical requirements for a project
- Act as the main point of contact for the client on behalf of Almac Project Services throughout the partnership
- Maintain and track project plan(s) and project deliverables
- Set and manage expectations on project among internal and external stakeholders

Workshop Description & Objectives

Identify the inputs needed to consider an end-to-end strategy for packaging, labeling and distribution across international markets.

1. Discuss supply planning with focus on the importance of forecasting for start-up activities.

2. Recognize strategies for waste reduction and improved reaction time to changing needs.

3. Examine digital tools, process harmonization, and the role of AI in clinical packaging.

Forecasting to Build a Unified Packaging & Labelling Strategy

Forecasting

Forecasting lays the groundwork of study requirements, the blueprint to a home.

Essential for understanding the goals of the clinical trial, creates a vision for the physical and digital supply chain, and ensures that all contractors are working off the same requirements.

Forecasting includes defining the 5 W's:

Who, What, When, Where, Why

Forecasting

Who – Key stakeholders and responsibilities?

What – Strategy to achieve the desired outcome? Drug (strength, form)? Mechanisms for development, testing, feedback, modification? Drug quantity, stability, and temperature and how impact to strategy? Lead times?

When – Start dosing? Drug available, safe, and stable? Region-, season-, or event-specific trial? Milestones? Results?

Where – Target patient population? Geographic / regional considerations or concerns? Feasibility and recruitment assessments known and understood? Local support?

Why – Relevance to packaging and labeling strategies; drug assignment and dispensation? Impact to the patients, trial, budget if incorrect forecast? Forecast adjustments with the least amount of impact?

Almac is the **How**.

Stakeholders

When it comes to clinical supplies, the expectations are usually not complicated…

For Sponsors / CROs…

"We just want the drug to be packaged/delivered correctly, in the right conditions, at the right time within the right costs."

For the Investigators / sites…

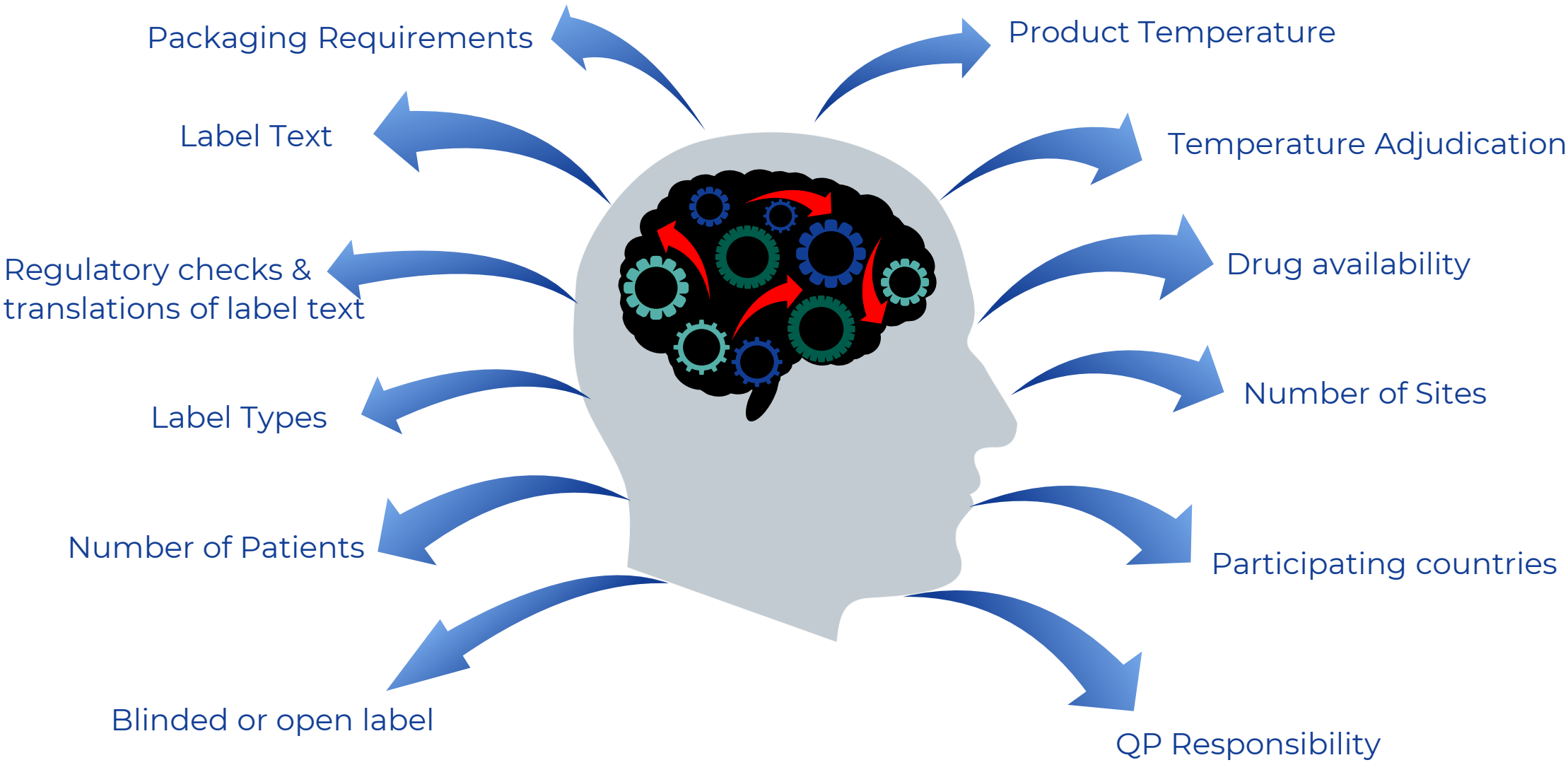
"We just want our patients to get their treatment on time as per the agreed protocol & schedule."

For patients…

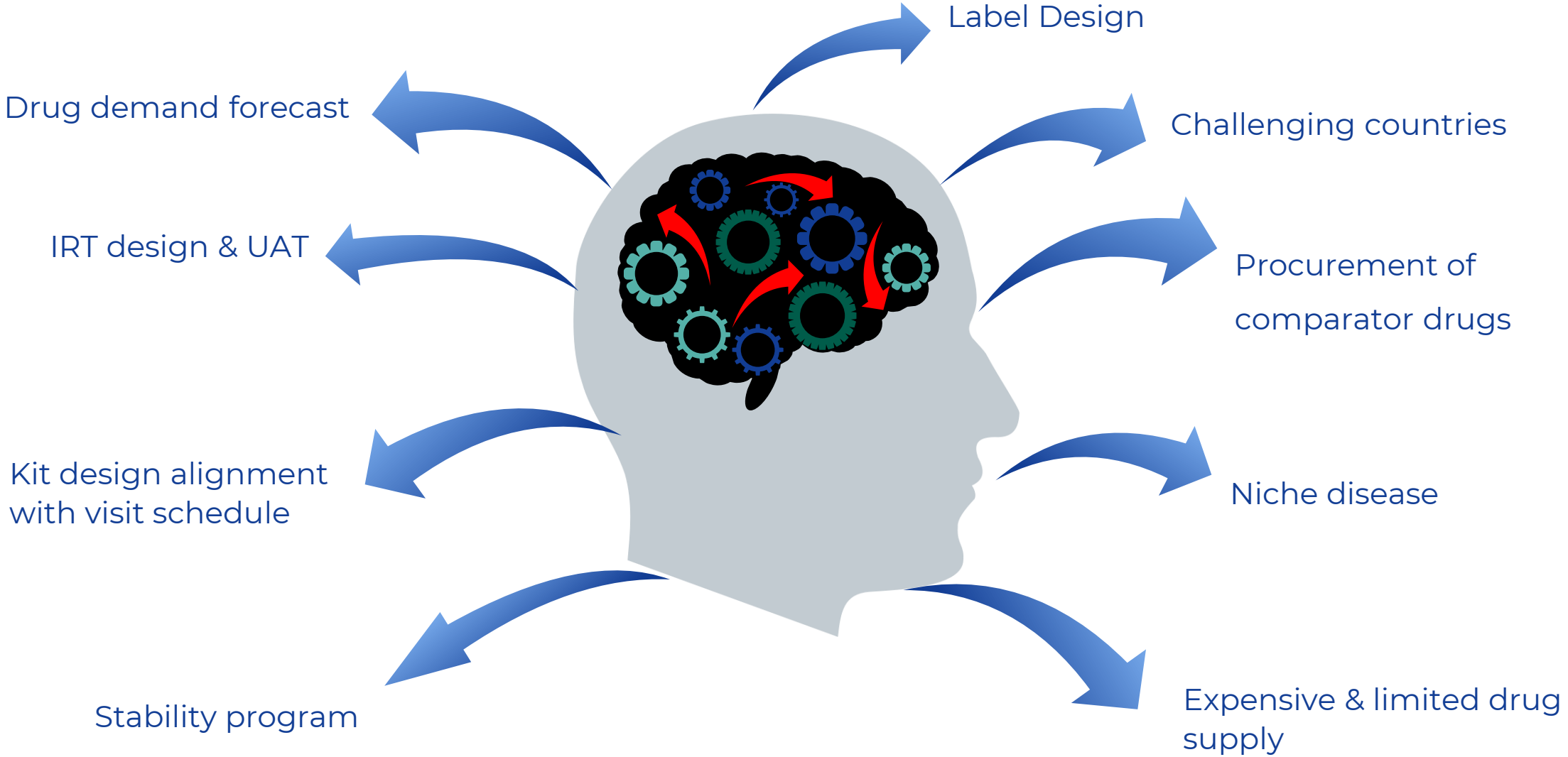
"We just want to have access to the drug for another chance at life."

Simple outcomes. However, it rarely turns out to be a simple journey for many in any clinical trial…

Essential Factors to consider in Study Set-up



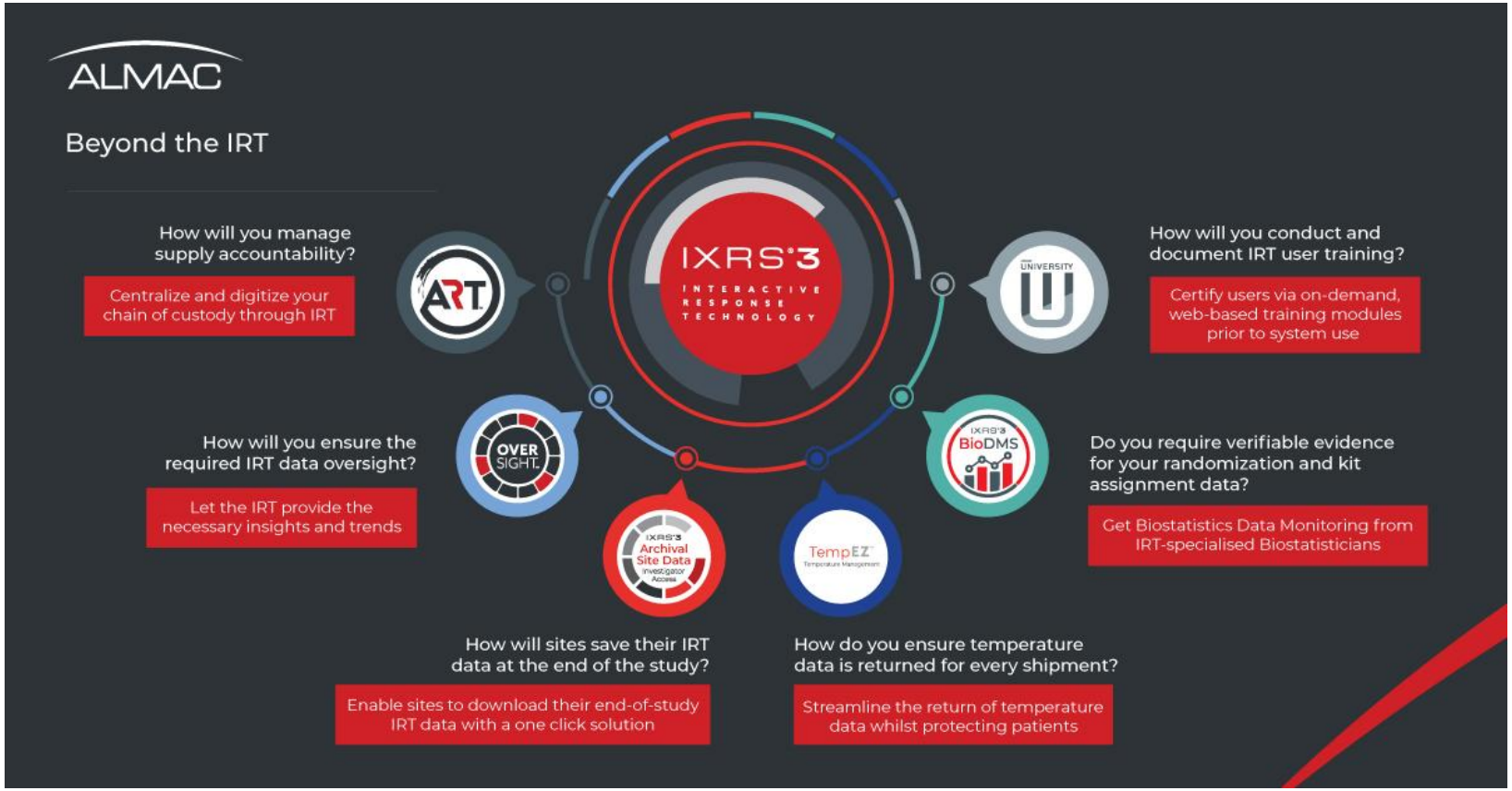
Navigating challenges in study scope and design



Digital Supply Chain Planning

Familiar with role of an IRT?

Interactive Response Technology (IRT) is how your clinical supplies can be digitally managed. This is a system that is built to the specifications of your trial to track patient material from depot to patient assignment.



Packaging Configurations

Remember those 5 W's?: **Who, What, When, Where, Why**

Stability, **A**dministration, **P**resentation

- Patient population and capabilities
- Local regulatory requirements
- Dispensation unit of measure (UOM)
  - align the physical supply chain and the digital supply chain UOM.
- Dosing schedule
- Use of commercial / comparator and regulatory requirements
- Site storage capabilities

Consider how often packaging need to be planned; expiry events? How are these tied back to your forecast?

Need a hand figuring this out? Just ask Almac!

Labelling Options

- Single Panel
  - Ideal for single country
  - Option for multi-country, multi-language (space permitting)
- Booklet
  - Ideal for multi-country, multi-language
  - Belgium (5 languages)
- Combination strategy
  - Is one country starting 2+ months ahead of other countries?
  - Do all countries play nice in the sandbox with each other?
- Labelling sensitivities
  - China, Taiwan, Hong Kong

Combining Packaging and Labelling

- Bulk Manufacturing
  - Packaging terms: packaging and labeling material in large batches; pre-made for shipping requests

    Pizza: take-and-bake, “Grab-and-Go” pizza; whole pizza or slice options that are pre-configured at your favorite slice shop, grocery store, Whole Foods, Costco, etc.

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- Just In Time Labeling (JTL)
  - Packaging terms: material previously packaged and labeled but requires simple modification prior to shipment to site
    Pizza: walk into a pizza shop for pepperoni slice; cheese is available, but can add pepperoni to your slice upon order


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    - Pizza: walk into a pizza shop for pepperoni slice; cheese is available, but can add pepperoni to your slice upon order

- Just In Time Manufacturing (JTM) or Almac ADAPT™
  - Packaging terms: packaging and labeling material upon site order
    - Pizza: personalized; made fresh on the spot to individual specifications

Factors That May Impact Costs

Unknown or changing country list

Comparators: sourcing, re-packaging, re-labelling

Ancillaries: Sourcing, distribution, dispensation

Reduced supply = more distribution

Unknown or changing vendors, partners

Break


Side Stretch
Spinal Twist
Cow Face Pose
Cow Pose
Cat Pose
Forward Fold
Figure 4 Stretch
Neck Side Stretch

Case Study: Group Exercise & Discussion

10-15 mins

Case Study – Part 1

Background

Phase 3 blinded study, 300 subjects

13 countries (US, EU, APAC); US FPI Jun, ROW FPI Oct

Treatment to go home with subject, 2x per day solid oral dose

Almac to blister, wallet, label treatment (tablets)

Challenge

Packaging configuration? Need to consider visit windows with ±3 days

Solution

	Visits (Days)							
Study Period	Screening	Randomization	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	EOS
Study Visit (Days)	-28 to -1	0	7 (± 3)	14 (± 3)	21 (± 3)	28 (± 3)	56 (± 3)	84 (± 3)
Informed Consent	X							
Subject Number Assigned	X							
Physical Exam	X							
Medical History	X							
Subject Randomization		X						
Treatment Dispensation			X	X	X	X	X	

What is your proposed packaging configuration? Labelling method? What risks can you identify?

Case Study – Part 1

Background	Challenge	Solution
Phase 3 blinded study, 300 subjects	Packaging configuration? Need to consider visit windows with ±3 days	Review the Schedule of Events & dosing visits
13 countries (US, EU, APAC); US FPI Jun, ROW FPI Oct		Identify largest visit windows with ± days considered
Treatment to go home with subject, 2x per day solid oral dose		Weigh packaging options vs dispensing options
Almac to blister, wallet, label treatment (tablets)		Consider and build-in IRT modifications

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Subject Randomization		X						
Treatment Dispensation			X	X	X	X	X	

Packaging Option 1

- 7x2 wallet design
- Dispense 2 kits at V1, V2, V3 + 5 kits at V4, V5
- Total kits per subject (V1 - EOS) = 16 wallets (224 tablets)
- What is your risk of waste? Patient compliance?

Directions	Day	AM	PM
Take 1 tab in AM and 1 tab in PM, 12 hours apart	1		
	2		
	3		
	4		
	5		
	6		
	7		

Packaging Option 2

- 10x2 wallet design
- Dispense 1 kits at V1, V2, V3 + 4 kits at V4, V5
- Total kits per subject (V1 - EOS) = 11 wallets (220 tablets)
- What is your risk of waste? Patient compliance?

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Labelling Option 1

- Booklet only

Labelling Option 2

- Single Panel (US) and Booklet (ROW to include US)

Considerations and Risks

- Who is providing the Final Master English Label Text and when will it be available?
- Who is responsible for Regulatory Review and Translation of label text and when are those files available?
- How long does it take for Regulatory Review and Translations at the sponsor / client vs CRO vs Almac?
- How long does label proof (artwork) development take?
- What is the lead time for printing different label types?
- What are the cost implications and impact to booklet labels if the country list is not finalized yet?

Case Study – Part 1

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What other packaging & labelling configurations did you brainstorm? Other risks?

Case Study – Part 1

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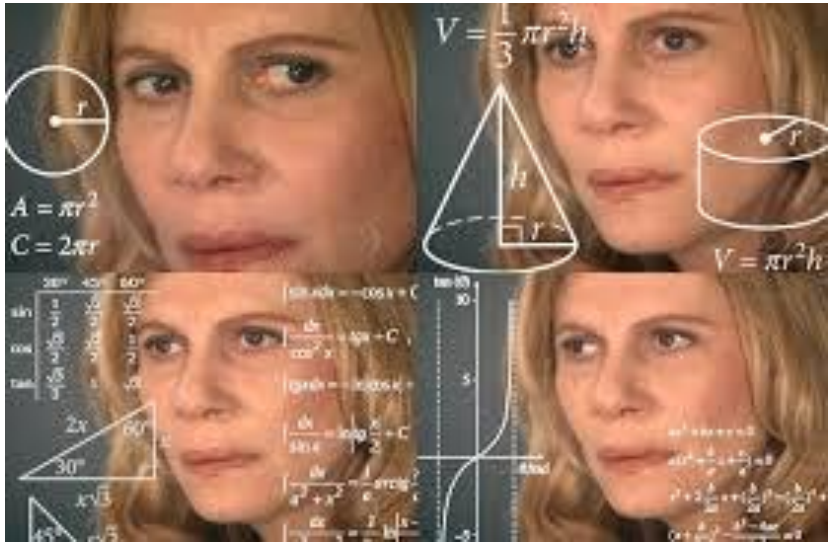
Treatment Dispensation			X	X	X	X	X	

Other pack & label configurations, risks presented by group:

Packaging Option 1: 2x7
Non compliance - Missed doses due to schedule changes
Waste/cost

Packaging Option 2: 2x10
Non compliance/safety issue - Overdose
Assumed waste/cost (actually less)



I NEED A BREAK!

10 mins

Waste Reduction Strategies and Planning for Change

Case Study – Part 1

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What does waste management mean to you?

- Fewer unused drugs at sites
- Fewer kits packaged
- Reduced number of shipments
- Reduced storage costs
- Reduce waste of expired material

Common Challenges During Supply Chain Set-Up and Maintenance

- Information readiness
  - What is still an assumption vs what is known?
  - How many stakeholders need to have access to this information? How will this information impact contracts, services, timelines with vendors?

- Relationships and Communication
  - Do your relationships support open, transparent, swift communication?
  - Are stakeholders expectations and goals aligned with you? With each other?

- Recruitment forecasting
  - A forecast is a guesstimate

- Regulatory
  - Timing of submissions
  - Changes to requirements, feedback from submissions and impacts to the protocol → downstream affect to vendors

- Funding and Budget
  - Changing landscape for federal funding
  - Evolving risks and ROI needs with private investments

Storage Planning

What do I need to think about to determine where I want to store my material?

- Enrollment forecast vs actual
  forecast adjustments → inventory checks, IRT checks
- Expiry planning
- Distribution method: frontloading site stock vs smaller, more frequent / controlled resupplies
- Time Out of Conditions (TOC) and handling requirements

Storage Planning

What do I need to think about to determine where I want to store my material?

- Enrollment forecast vs actual
  forecast adjustments → inventory checks, IRT checks

Example:
Global diabetes trial

- Planned: 3 sites, 10 subjects each site
- Actual: 3 sites, 40-45 subjects each site
- Country-specific ancillary material sourcing from third-party vendor with 4-week lead time
- Weekly updated enrollment projections
- Screening to Randomization window: 28 days
- Scrambled to purchase ancillaries, ship to sites prior to first subject dose

As a supply chain manager, how could I have saved myself some gray hairs and sleepless nights?

Storage Planning

What do I need to think about to determine where I want to store my material?

- Enrollment forecast vs actual
  forecast adjustments → inventory checks, IRT checks

Example:
Site inventory vs IRT inventory with a sprinkle of site non-compliance

- Blinded study
- Material stored in local in-country depot
- Site personnel would pull kits from shelf, administer to subject, then register the visit in the IRT **or** not register the visit in IRT at all
- Resulted in a huge discrepancy between actual physical inventory and IRT inventory
- Lead to IRT not raising resupply orders, site stock-outs

How would you tackle this issue as a supply chain manager?

Distribution Method

What do you think are key pillars of distribution?

What key factors do you feel can impact how you map out a distribution plan?

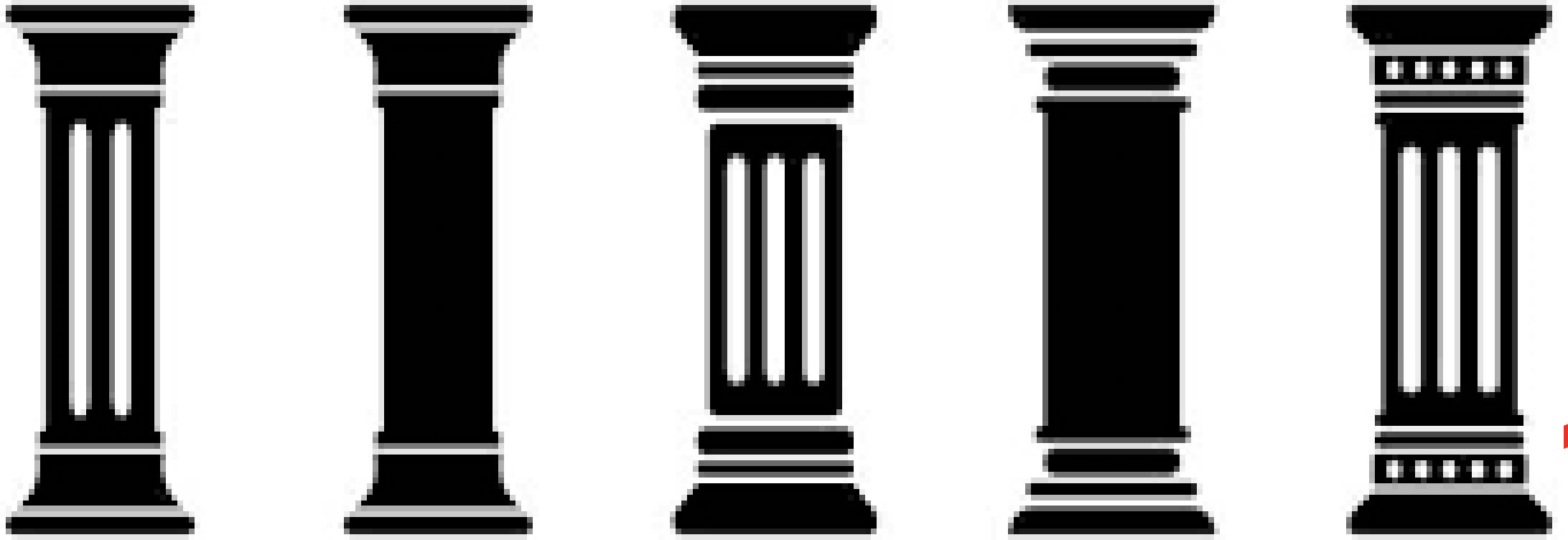
Depot Locations

Transit Routes

Transit Times

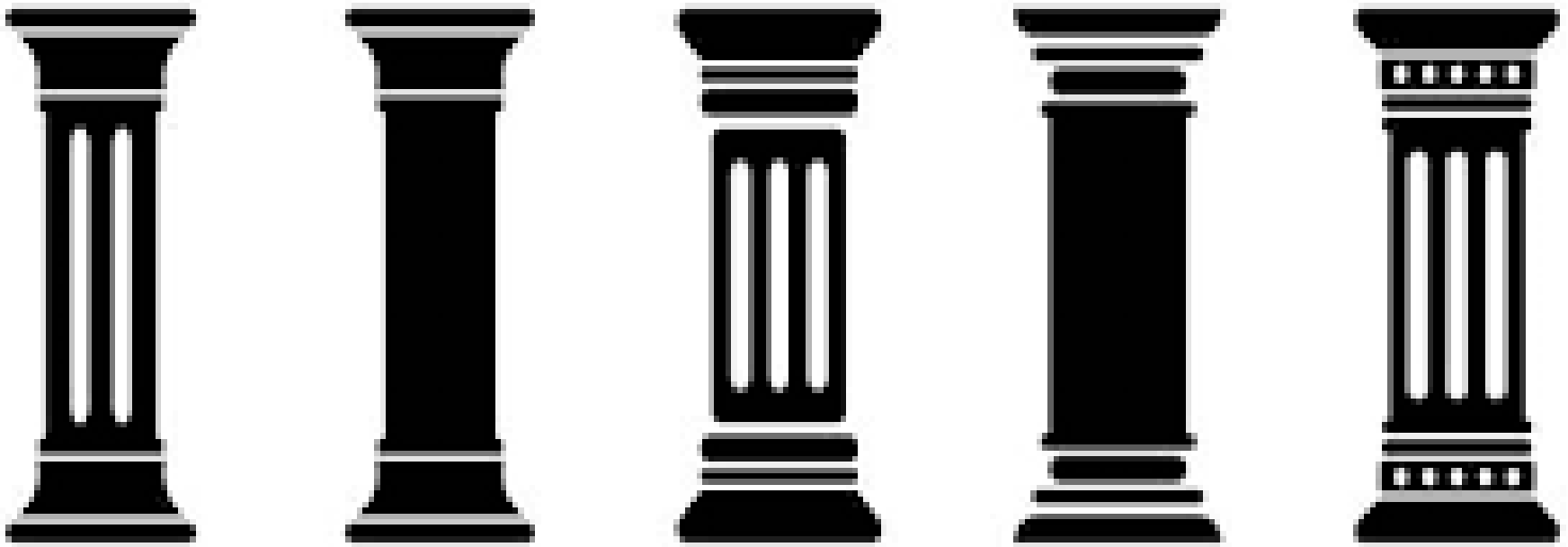
Import Req's

Temperature



Distribution Method

Depot Locations | Transit Routes | Transit Times | Import Req's | Temperature



Example:
"Distribution is half of my budget"

- Phase 1, Blinded, US-only study, rare disease
- Supply chain manager is unblinded
- Heavy sponsor emphasis on waste reduction; any material leftover after the trial can be used for another program
- Resulted in bi-weekly (every other week) review of projected vs actual enrollment; small, frequent shipments to sites; very minimal site safety stock (2 units active + 2 units PTM)

Where are you willing to increase your budget to control waste?

Project Management

Where are you willing to bend?

In a perfect world, bending is not required. But that's not how clinical trials work. We have to be flexible, nimble, and willing to compromise for the benefit of our patients.

Are you willing to pay a little more for High Quality work to be Completed Quickly?

Are you more focused on Controlling your Budget and ensuring a High-Quality output?

Or are you prepared to risk the quality of the work for a Low-Cost, Fast-Turnaround result?

Is the method of focus sustainable long-term and across multiple stakeholders?

Project Management

Where does this fit in the project management triangle?

Where are you willing to bend?

Example:
Bulk Manufacturing

- Packaging terms: packaging and labeling material in large batches; pre-made for shipping requests
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Where does this fit in the project management triangle?

Project Management

Where are you willing to bend?

Example:
Just In Time Manufacturing (JTM) or Almac ADAPT™

- Packaging terms: packaging and labeling material upon site order
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Where does this fit in the project management triangle?

For all challenges throughout a clinical trial the focus is on the **patient** and ensuring that **quality** product is **delivered on time.**

Clinical Supply Success is not built upon just one solution. A **flexible & robust approach,** supported with global capabilities, makes the difference to your journey.

Break


Side Stretch
Spinal Twist
Cow Face Pose
Cow Pose
Cat Pose
Forward Fold
Figure 4 Stretch
Neck Side Stretch

Case Study: Group Exercise & Discussion

10-15 mins

Case Study 1 – Part 1 Recap

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Labelling Option 2

- Single Panel (US) and Booklet (ROW to include US)

Case Study – Part 2

Background

- Phase 3 blinded study, 300 subjects
- 13 countries (US, EU, APAC); US FPI Jun, ROW FPI Oct
- Treatment to go home with subject, 2x per day solid oral dose
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Challenge

- Where should treatment be allocated, stored if country list is not yet finalized?

Solution

What is your proposed distribution strategy? What risks can you identify?

Case Study – Part 2

Background

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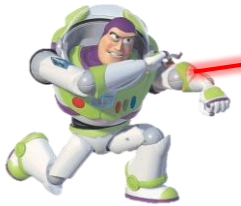
Solution

Hint!



What is your proposed distribution strategy? What risks can you identify?

Case Study – Part 2

Background	Challenge	Solution
Phase 3 blinded study, 300 subjects	Where should treatment be allocated, stored if country list is not yet finalized?	If countries not defined, define regions
13 countries (US, EU, APAC); US FPI Jun, ROW FPI Oct		Identify CDMO owned- or partnered-facilities
Treatment to go home with subject, 2x per day solid oral dose		Variation in transit time if approached from a central depot vs regional depots
Almac to blister, wallet, label treatment (tablets)		Consider Import License requirements & IRT settings

Case Study – Part 2

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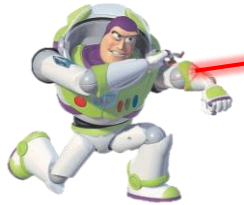


13 countries (US, EU, APAC);
US FPI Jun, ROW FPI Oct

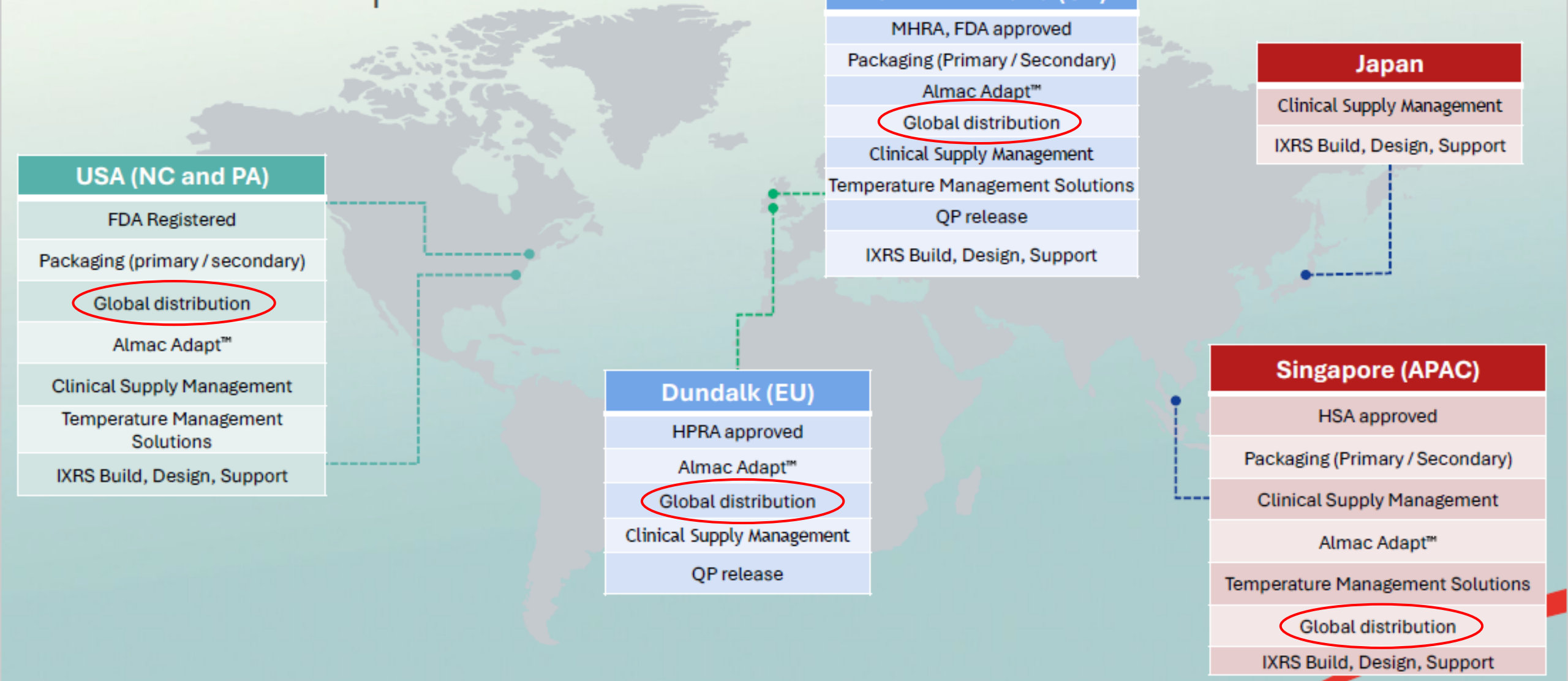
Distribution Option 1

- Central distribution from one facility

Distribution Option 2

- Distribution from several regional facilities

Our Global Capabilities



USA (NC and PA)

- FDA Registered
- Packaging (primary / secondary)
- Global distribution
- Almac Adapt™
- Clinical Supply Management
- Temperature Management Solutions
- IXRS Build, Design, Support

Northern Ireland (UK)

- MHRA, FDA approved
- Packaging (Primary / Secondary)
- Almac Adapt™
- Global distribution
- Clinical Supply Management
- Temperature Management Solutions
- QP release
- IXRS Build, Design, Support

Japan

- Clinical Supply Management
- IXRS Build, Design, Support

Dundalk (EU)

- HPRA approved
- Almac Adapt™
- Global distribution
- Clinical Supply Management
- QP release

Singapore (APAC)

- HSA approved
- Packaging (Primary / Secondary)
- Clinical Supply Management
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- IXRS Build, Design, Support

Case Study – Part 2

13 countries (US, EU, APAC);
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Distribution Option 1
- Central distribution from one facility

Distribution Option 2
- Distribution from several regional facilities

Considerations and Risks
- How much drug do I have, how stable is it, and can I afford to split it amongst several storage facilities?
- What is transit time when comparing Option 1 and Option 2 and how will that impact my decision?
- Am I able to provide my own Importer of Record (IOR) or do I need to leverage a vendor to use their services?
- Who is responsible for acquiring, tracking, renewing Import Licenses?
- Are import licenses based on a duration (i.e. 1 year), import quantity, or combination of both?
- How quickly can I shuffle inventory between regional facilities if and when my enrollment projections change?
- Where can I minimize waste (material, budget, time)?

Fewer unused drugs at sites

Fewer kits packaged

Reduced number of shipments

Reduced storage costs

Reduce waste of expired material

Case Study – Part 2

Background	Challenge	Solution
Phase 3 blinded study, 300 subjects	Where should treatment be allocated, stored if country list is not yet finalized?	If countries not defined, define regions
13 countries (US, EU, APAC); US FPI Jun, ROW FPI Oct		Identify CDMO owned- or partnered-facilities
Treatment to go home with subject, 2x per day solid oral dose		Variation in transit time if approached from a central depot vs regional depots
Almac to blister, wallet, label treatment (tablets)		Consider Import License requirements & IRT settings

What other distribution strategies did you brainstorm? Other risks? Ways to reduce waste?

Case Study – Part 2

13 countries (US, EU, APAC);
US FPI Jun, ROW FPI Oct

Distribution Option 1

- Central distribution from one facility

Distribution Option 2

- Distribution from several regional facilities

Other distribution strategies, risks, ways to reduce waste presented by group:
Distribution Option 1: Central Depot
Less flexibility/speed
Import problems

Distribution Option 2: Regional Depots
Higher cost
Reverse logistics issues should enrollment not follow the forecast

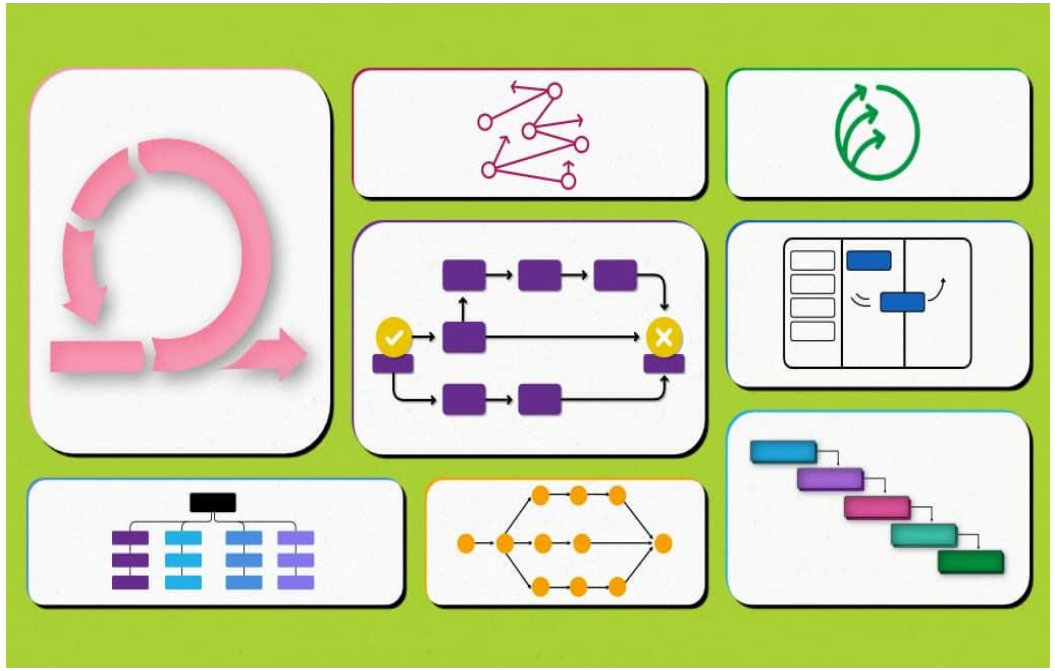
I NEED A BREAK!

10 mins

Digital Tools and Process Harmonization

Tools & Harmonization
Industry Tools

- IRT and reports
- Project management tools (Slack, Smart Sheet, MS Project, Teams, Zoom, etc.)
- Portals to register clinical trials: ClinicalTrials.gov (US), Integrated Research Application System (IRAS) (UK), Clinical Trials Information System (CTIS) (EU), etc.
- Clinical Trial Regulation platform (EU)
- Portals to electronically trace unique prescription medications, ensure proper anti-tampering measures are considered on packaging, and protect consumers from counterfeit or contaminated drugs
- US - Drug Supply Chain Security Act (DSCSA) portal
- EU - Falsified Medicines Directive (FMD) portal (Directive 2011/62/EU) or Delegated Regulation portal (Regulation EU) 2016/161)



Tools & Harmonization
Almac Tools

PEOPLE
Cross-organizational
Team Collaboration

CORESHARE
DOCUMENT COLLAB

PROCESS
Automated Task
Management

TEMP EZ

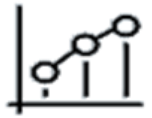
LABEL APPROVAL
SYSTEM

Vault

MY PROTOCOLS

ALMAC DART™

DATA
Reporting & Visualization



MY DASHBOARD

MY CLINICAL
SUPPLIES

Emerging Tools

What about other, emerging tools, like AI?

Emerging Tools and Potential

Potential for AI in Clinical Trials

- Protocol design
  - Predictive analytics for protocol development
  - Identifying eligible patients and improved diversity and representation in trials
- Forecasting
  - Machine learning models to review protocols and predict drug supply needs, optimizing inventory and reducing waste
- Label text development or review
- Packaging requirements based on protocol
- Distribution strategy based on enrollment projections
  - Use AI for route planning and logistics
  - Import/export documentation

Emerging Tools and Potential

AI Advantages

- Completion of tasks that would take humans a long time to complete
- AI can pull data from previous studies to assist with future study development
- AI can review large amounts of data uploads and provide ‘outliers’ for human review
- Long-term goals:
  - Increased efficiency and cost savings
  - Improved accuracy and faster decision-making

Emerging Tools and Potential

Broader AI Challenges

- Technical issues and integration with existing systems
- Limited benchmarks and how best to evaluate AI performance
- Data privacy and security concerns with access to sensitive patient data
- Regulatory and ethical considerations
    - Ensuring AI decisions can be audited and accountability for mistakes
- Cost to develop, implement and maintain AI systems

ALMAC

Supply With Care™

Thank you for joining us today!

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