



*“Driving Innovation and Technology  
in the Bio-pharma Supply Chain”*



*Because life depends on us™*

## TRACK 1

# “Outsourcing the Clinical Supply Chain: Is a Single Provider Strategy the Solution?”

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***BUILDING SUPPLY CHAIN EXCELLENCE END TO END***



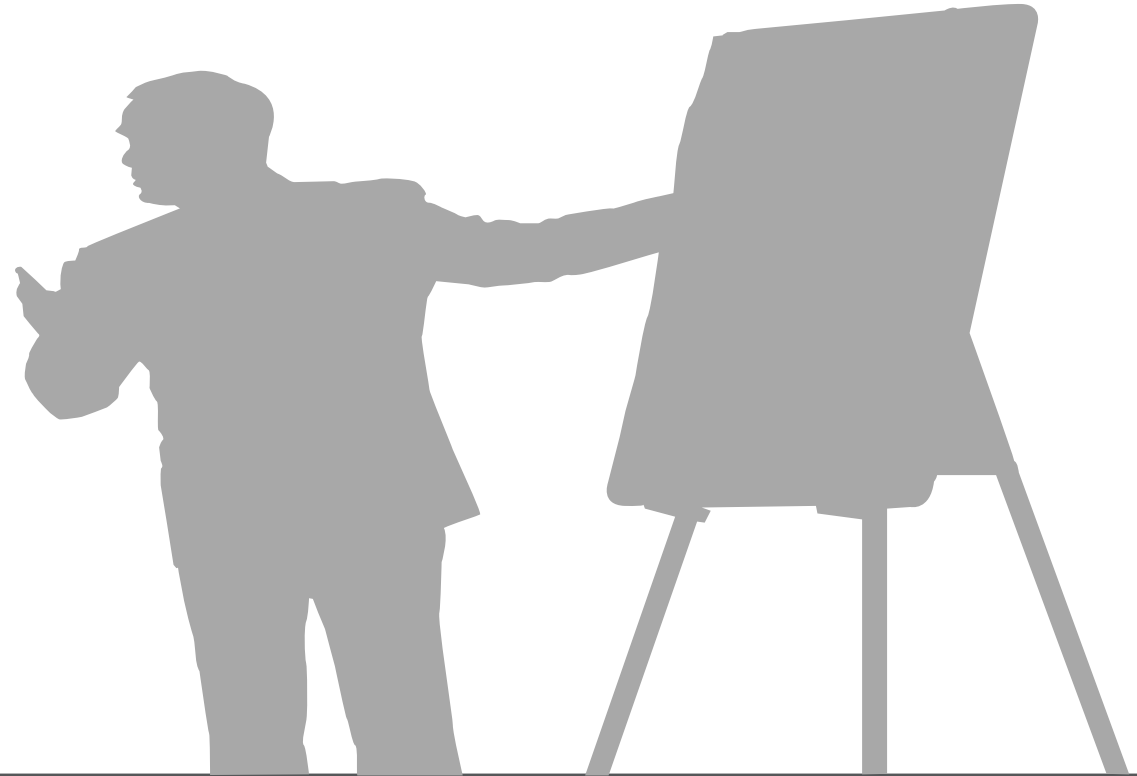
A Thermo Fisher Scientific Brand

# Clinical Trials Supply Chain – Clinical Supplies Sourcing: Is the industry evolving to single provider relationships ?

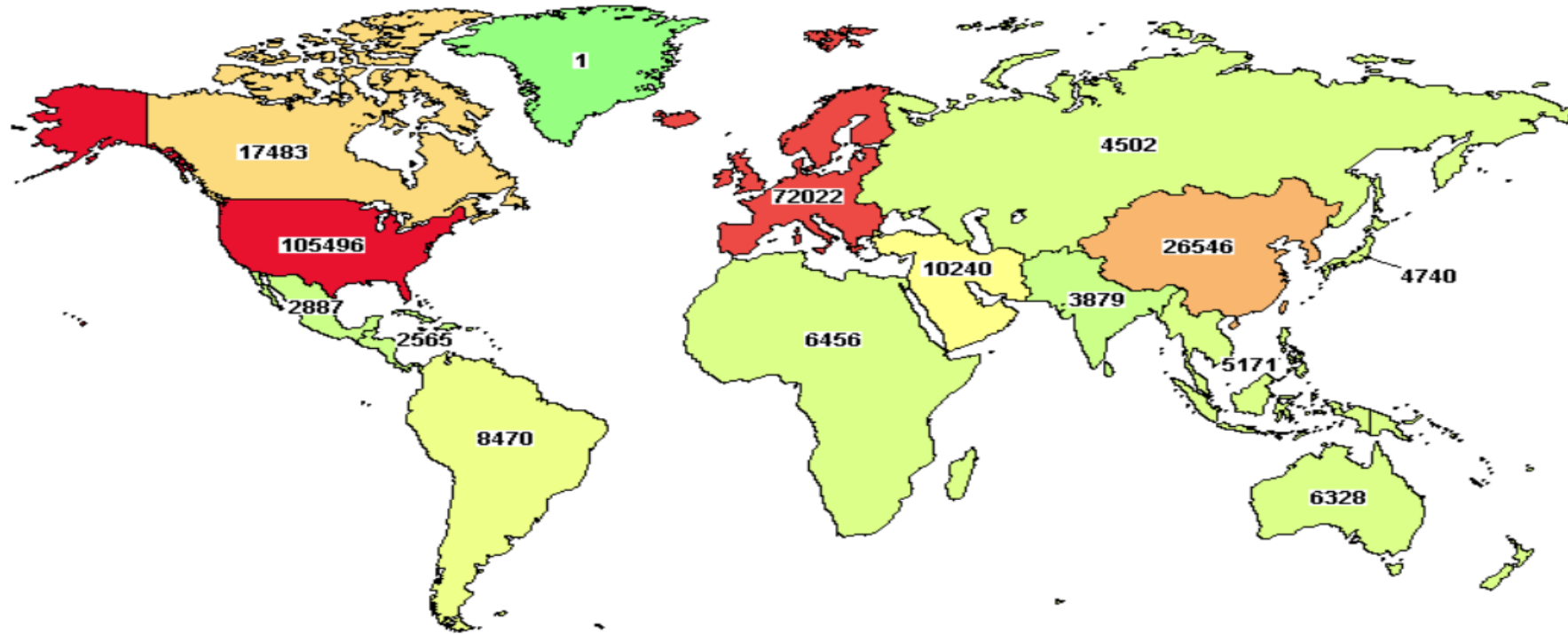
12 October 2017  
*Jim Benkendorf*

# Today's Agenda

- Industry Trends
- Outsourcing Options
- Scenarios/Case Studies
- Factors for Success
- Considerations & Tips



# Industry Trends - Clinical Trials by Country, Oct 2017



**Location** **Number of Registered Studies and Percentage of Total**  
(as of October 03, 2017)

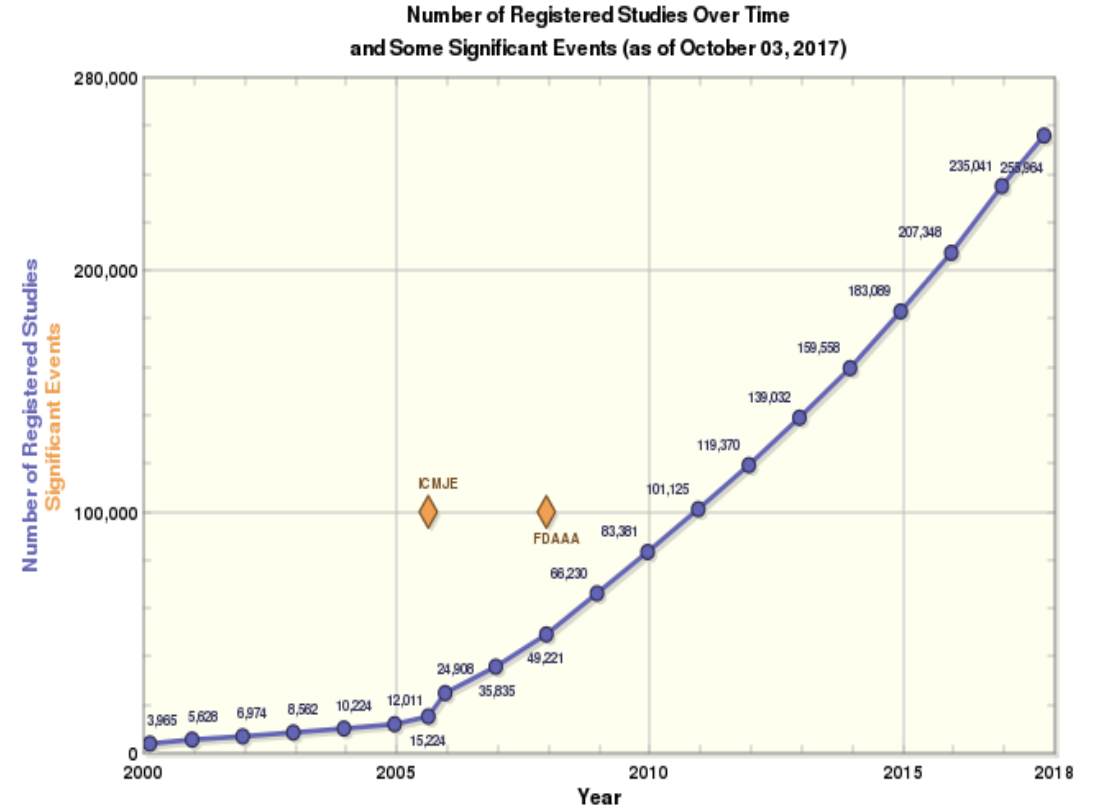
Non-U.S. only	120,226 (47%)
U.S. only	91,488 (36%)
Not provided	30,242 (12%)
Both U.S. and non-U.S.	14,008 (5%)
<b>Total</b>	<b>255,964</b>

Source: <https://ClinicalTrials.gov>

# Outsourcing Drivers

## Why outsource ?

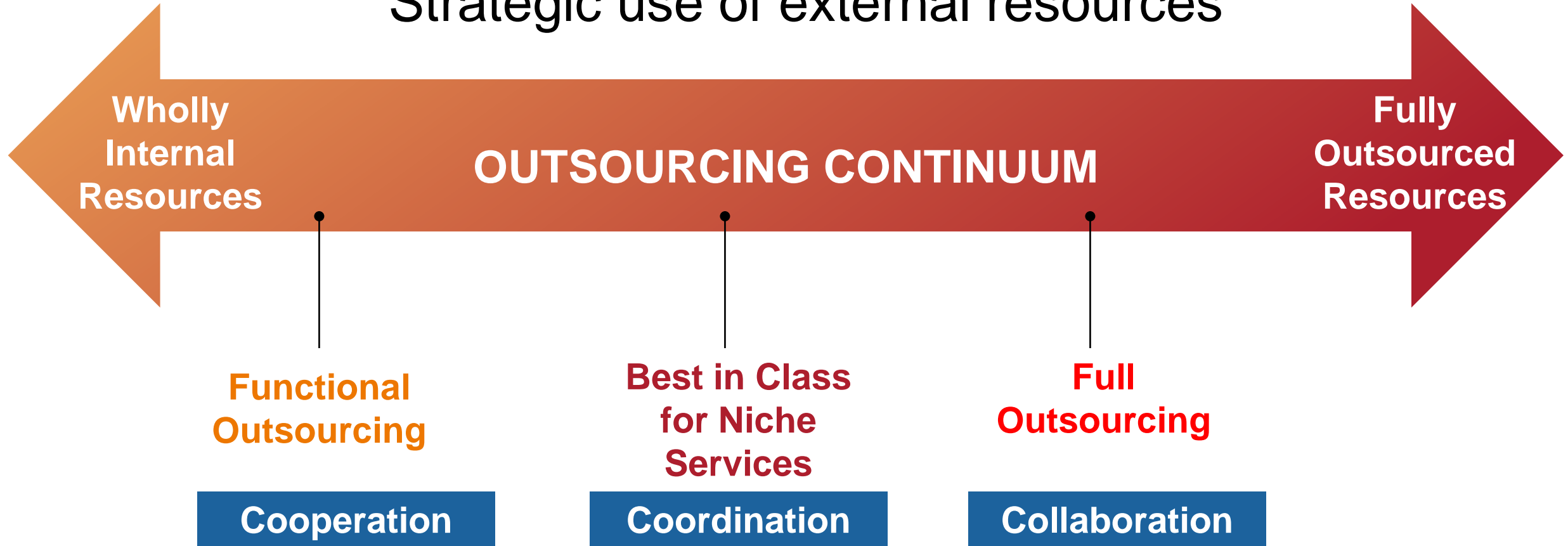
- ✓ Less internal capability to do it all: focus on core competencies, conserve capital
  - ✓ Reduce overhead
- ✓ Necessity: access to expertise, capabilities & capacity
- ✓ Greater project complexity: innovative therapies, cold chain requirements, regulatory hurdles
- ✓ Foster innovation & speed to market
- ✓ Proven, established relationship & partnership with a specialist provider



Source: <https://ClinicalTrials.gov>

# Industry Trends - Outsourcing Models

## Strategic use of external resources



## Advantages

- Choose specialist providers for a particular service: IRT, packaging, labelling, logistics (best in class)
- Choose specialist for a particular therapeutic area (CRO)
- Access to expertise
- Access to remote locations: may work with a locally based provider
- Mitigate risk: *“avoid all of your eggs in one basket”*

## Disadvantages

- Increased complexity of managing relationships, handling
  - Greater supplier management burden
  - Diverse vendor processes
- Training staff on multiple vendor system or tools
- Stability/Longevity risk? Will a smaller niche provider go out of business or be acquired by another company?
- Unlikely “best in class” in multiple areas
- High turnover in smaller firms can mean loss expertise
- Less depth of talent may impact study

## Advantages

- Reliability: Vendor takes total responsibility for everything
- Stronger long term relationship: investment of time and resources
- Working in partnership: Escalation easier, issue resolution easier
- Greater continuous improvement effort
- Better integration of information, systems and approaches
- Less time/resources dedicated to vendor management
- Better pricing through volume discounts; application of automation or technology solutions

## Disadvantages

- Potential high risk if not actively managed
- Totally dependent on that one vendor
- Vendor may not be able to meet timelines
- How can you guarantee level of service from that vendor?



# Scenario One

## Situation:

- Global Biopharma company
- Multi product portfolio
- Conducts clinical research in the USA, Europe, Asia and LATAM with Orphan therapies in Africa

## Seeking vendor to:

- Complement internal resources: project management and small scale production
- Provide local specialist expertise for cold chain in challenging destinations (e.g Africa)

**Solution: Alignment match to client culture- multi vendor approach**

## Benefits to the Sponsor:

- Flexibility: access to scalable capacity when required
- Application of appropriate technology for larger scale runs
- Access to specialist in key areas: geographic or therapeutic area
- Larger exposure to orphan products to jump start solutions generation
- Global coverage combined with on-the-ground local regulatory and practical know-how with key contacts
- Importer of record and regulatory support
- In time the relationship may evolve to a hybrid or full service regionally

**Multi-Vendor  
Approach**

# Scenario Two

## Situation:

- Small biotech company on the West Coast of the USA
- Innovative therapy for oncology
- Wants to conduct clinical research in the USA, Western Europe and LATAM

## Seeking vendor to:

- Source comparator
- Advise on IRT and perform UAT
- Manage and execute multiple studies:entire program
- Co-ordinate accountability, returns and destruction

## Solution: Ideal approach - Single vendor, full service

## Benefits to the Sponsor:

- Strategy: Single relationship to manage freeing internal resources for scientific excellence
- Cycle time: Reduce time and cost of delivering IMP to market
- Access to technical skills and operational expertise in this therapeutic area
- Local import/export knowledge of complex LATAM region
- Definition of Supply strategy: appropriate hubs and responsiveness to avoid stock out, minimise waste of expensive product and comparator
- Knowledge transfer: application lessons learned to subsequent studies - offer operational insight to improve designs and processes
- Cost synergies through application productivity enhancements & innovation
- Higher engagement and ownership; earlier intervention and recommendations

**Full  
outsourcing  
model**

# Case Study: Technology Application – Just-In-Time solution

## SITUATION

- Top 10 Biotech company faces challenges with inventory availability, including comparator
- Multiple protocols in program using the same core products
- Strategic driver- to control key supply chain process

### Goals

- Waste reduction
- Minimising buffer inventory across protocols
- Objectives of responsiveness, speed, quality

## RESPONSE

- Customise our bespoke IT system to create validated controlled process that is Annex 13 compliant
- Apply principles of both Lean and Agile
- Ensure QP release doesn't become a constraint
- Standardise process to reduce risk

### Client Benefits

- Capability to pool across programme achieved, delivering reduction in inventory
- Demonstrated reduction in number site shipments

## VALUE DELIVERED

- Lean processes - to meet rapid response timelines for documentation generation and production
- A scalable process - responsive to demand fluctuations
- Automated processes controlled by bespoke IT platform to:
  - Remove potential for human error
  - Ensure system checks and balances are performed and recorded
- A regulatory compliant process for
  - Labels
  - Regulatory Documentation
  - QP certification

# Successful Strategic Relationships Result In ...



- Individual Excellence
- Investment Return
- Interdependence
- Information Sharing/Best Practices
- Importance
- Integration
- Institutionalisation
- Integrity

# Consideration and Top Tips For Success...

1

Define operating principles and behaviours alongside metrics

2

Define decision-making rules and responsibilities

3

Ensure clarity of joint goals, objectives and alignment

4

Agree on timeframes for delivering results

5

Ensure structure and resources are organized to efficiently respond to business needs

6

Evolve Service Level Agreements to drive value not just commitment

- Metrics that matter

# Considerations and Top Tips For Success

7

Conduct SWOT analysis or FMEA to identify and mitigate risks

8

Clear escalation pathways with senior level engagement

9

Practice a continuous improvement philosophy

10

Encourage open communication and best practice sharing

11

Ensure business continuity, damage control & back up plans

12

Working together in partnership

# Questions

