CRO Contracting & Partnership Models

Almac Clinical Technologies

PCMG US Workshop

April 27 2017

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Agenda

- Overview of Almac Group

- Contracting Models (Pro's & Con's)
  A. Sponsor Contracts & Manages 3rd Parties
  B. Sponsor Contracts & CRO Manages 3rd Parties
  C. CRO Contracts & Manages 3rd Parties

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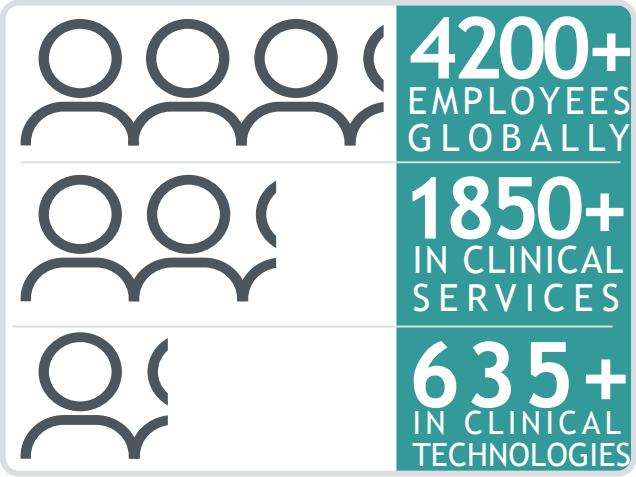
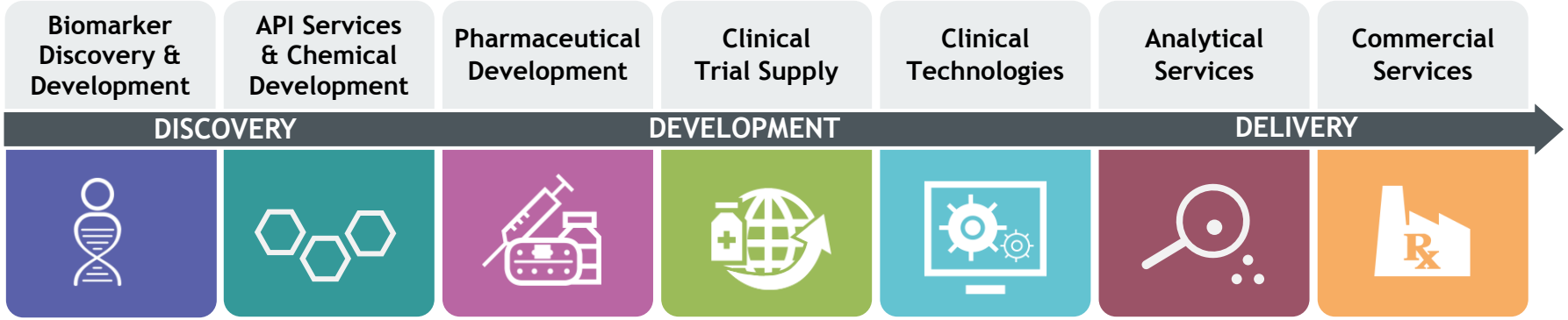
Almac Group

Almac is a privately owned, charitable trust

Global leader of drug development products and services

Our mission is to be your partner of choice, providing an array of innovative Clinical Solutions





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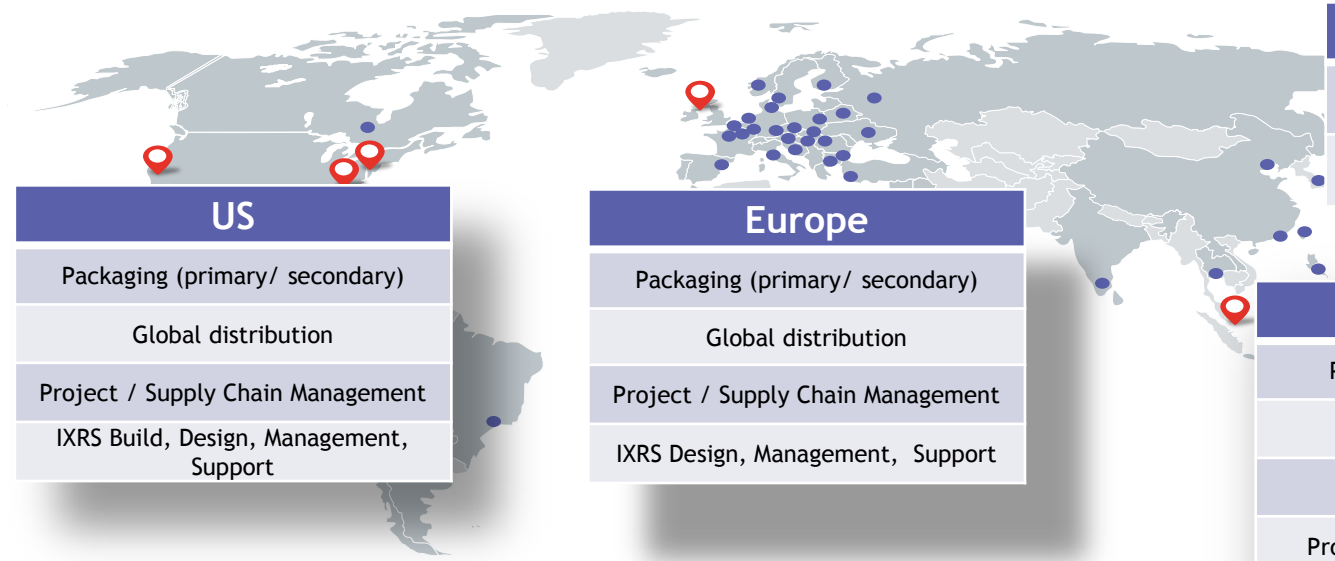
Almac Global Clinical & Technology Solutions



US

- Packaging (primary/ secondary)
- Global distribution
- Project / Supply Chain Management
- IXRS Build, Design, Management, Support

Europe

- Packaging (primary/ secondary)
- Global distribution
- Project / Supply Chain Management
- IXRS Design, Management, Support

Japan

- Project / Supply Chain Management
- IXRS Design, Management, Support

Singapore (APAC)

- Packaging (primary/ secondary)
- APAC distribution
- Global reach, Local Expertise
- Project / Supply Chain Management
- IXRS Design, Management, Support

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A. Sponsor Contracts & Manages All Parties

- Cons
  - Limited resources
  - MSA & contracting process may not be in place
- Pro's
  - Greater direct control over 3rd party
  - Well established standards
  - More continuity

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A. Sponsor Contracts & Manages All Parties

- Example A
  - Most common for us
  - Generally preferred

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B. Sponsor Contracts & CRO Manages 3rd Parties

- Con's
  - Less control over cost, quality, speed
  - Understanding of project requirements may differ
  - Need for authorization to proceed with CO's
  - Accountability for delivery of services can be unclear

- Pro's
  - Can work when governance structure is well established
  - Works well when CRO has dedicated Vendor Management group

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B. Sponsor Contracts & CRO Manages 3rd Parties

- Example B
  - Sponsor is Almac's #1 customer
  - Due to resource constraints, they've asked CRO to manage Almac for a particular program

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C. CRO Contracts & Manages All Third Parties

- Con's
  - Lack of direct management
  - CRO may still need authorization to proceed
  - Pricing may be less transparent
  - Volume of CO's may increase
  - Lack of internal resource who understands what we do
  - Conflicts of interest
- Pro's
  - Access to best in class providers
  - Ability to take advantage of volume based pricing
  - Greater leverage = better access to resources
  - MSA is already in place
  - Established contracting process
  - Many CRO's now have established Vendor Management

C. CRO Contracts & Manages All Third Parties

- Example C
  - Largest CRO customer
  - Vendor Manager v. no Vendor Manager
  - Level of sponsor involvement

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Summary and Closing

- Best Practices
  - In all cases, contracting to positive result for both parties requires these fundamental elements

a) Open lines of communication
b) Well defined RACI matrix
c) Agreement on project milestones and payment structure tied to them

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Thank You.

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