

What Do You Mean, You Need Equipment?

Demystifying the Complexities of
the Equipment Supply Chain



Jon Raven
Chief Commercial
Officer



Bryan Dunlop
Business Development
Manager, NA

70% of clinical trial delays are
due to supply chain issues



The real cost of trial delays



24h delay



\$40,000

in direct clinical trial costs



\$800,000

in potential drug sales per day



The Importance of Equipment is Often Underestimated

↙ **Bottom third**
Total category spend

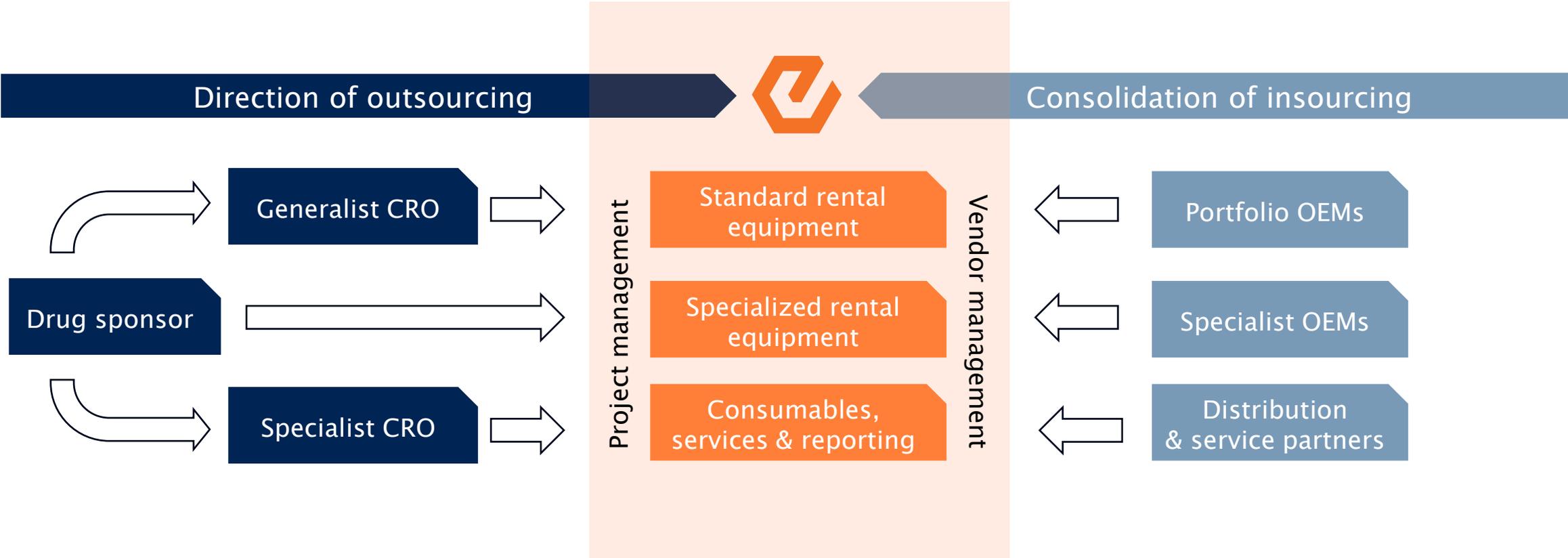
↗ **Top third**
Impact on project
timelines



What Supporting Role Does **Equipment** Play in Clinical Development?



Equipment Vendor Positioning Ecosystem



The Role of Equipment in Clinical Development

From the simple...



Spinning blood as part of screening

....to the more complex...



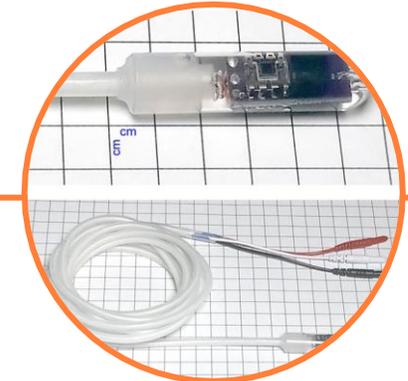
High-quality retinal images as part of primary endpoints

...through emerging therapy...



Gamma counter for treatment dose adjustment in radioligand therapy

...to the more unusual



Vaginal photoplethysmogram to measure female arousal as part of secondary endpoint



What Challenges Do We Face?

1. Adjusting for protocol amendments
2. Navigating global logistics and regulations
3. Considering sustainability
4. Choosing the right vendors



Adjusting for Protocol Amendments

- 57% of protocols have ≥ 1 substantial amendment
- 45% of amendments are avoidable
- Median cost to a phase III protocol is \$535,000¹



Adjusting for Protocol Amendments

Solutions

Pharma/CROs

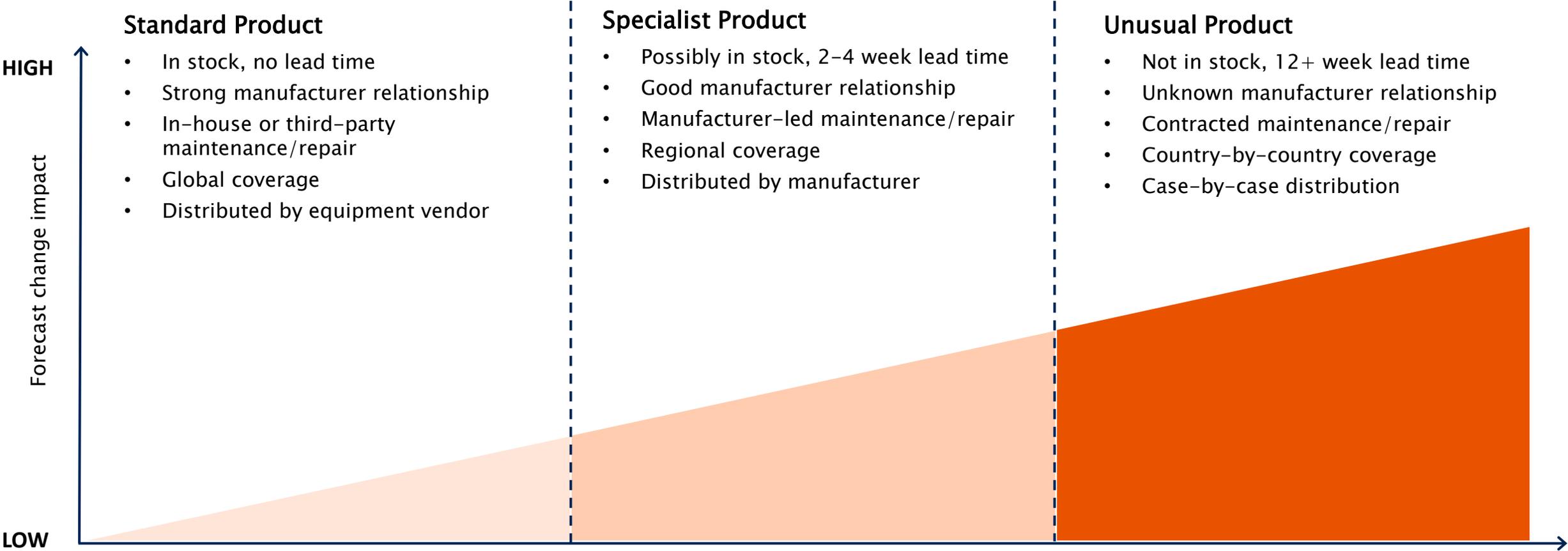
- ✓ Share protocols early
- ✓ Think at a program level as well as at a study level
- ✓ Budget for worst case but spend time on best case

Equipment vendors

- ✓ Protocol analysis
- ✓ Forecasting and resupply models
- ✓ Budget planning



Equipment Complexity = Higher Forecasting Impact



Navigating Global Logistics and Regulations

- 33 national and regional authorities for regulatory standards and practices¹
- Clinical studies in over 200 countries²
- MDR, GDPR, HIPPA all include regulations affecting equipment



Navigating Global Logistics and Regulations

Solutions

Pharma/CROs

- ✓ Consider study complexity
- ✓ Involve vendors early
- ✓ Consider what will be required at the end of the study for regulatory approval

Equipment vendors

- ✓ Global logistics coverage
- ✓ Regulatory documentation
- ✓ Allied partnerships e.g. IoR



IOR/EOR Services

Importer of Record (IOR)

- Compliance with import regulations
- Duties/taxes
- Import documentation

Exporter of Record (EOR)

- Compliance with export regulations
- Export declarations
- Export documentation

Why work with an IOR/EOR provider?

- ✓ Ensures compliance with global trade regulations, reducing legal and compliance risks
- ✓ Prevents customs delays and penalties
- ✓ Provides a seamless import/export process
- ✓ Simplifies tax and duty management
- ✓ Provides a legal entity for businesses without a local presence
- ✓ Streamlines cross-border shipping and logistics
- ✓ Ensures proper documentation and record-keeping



Considerations for Sustainability Improvements

- Regulatory pressure: EMA and FDA are incorporating sustainability into their guidelines
- Corporate responsibility: Pharmaceutical companies are striving for net zero or better in 5–10 years



Considerations for Sustainability Improvements

Solutions

Pharma/CROs

- ✓ Look for sustainability improvements in all part of the supply chain
- ✓ Qualitative and quantitative

Equipment vendors

- ✓ Rental vs purchase of equipment
- ✓ Consolidated shipments
- ✓ Shipping method



Sustainability Improvements

Product rental

- **Extended lifecycle**
 - Parts for repairs
 - Sustainable disposal

01

Circular economy

- **Newer models**
 - Improved energy efficiency
 - Eco-friendly materials

03

- **Consolidated shipping**
 - Reduced carbon footprint
 - Reduced costs

02

Requires more upfront planning, but creates long-term benefits



Vendor Choice and Equipment Continuity

- Fragmented supply networks make consistency and continuity a constant challenge
- A single substandard item—like a faulty device or equipment with missed calibration — can compromise an entire study



Vendor Choice and Equipment Continuity

Solutions

Pharma/CROs

- ✓ Consolidate vendors
- ✓ Seek real-time tracking for efficiency
- ✓ Think of wrap-around service requirements

Equipment vendors

- ✓ Strong breadth of product portfolio
- ✓ Provide real-time, online reporting



Picking the Right Vendors: What to Look For?

Supply assurance

- Manufacturer relationships
- Equipment maintenance and repair



Quality standards

- Good Clinical Practice (GCP)
- ISO 9001, ISO 13485



Technological ability

- Real-time portal
- Customer specific punch-out catalogues



Product/service innovation

- Service development for newer study types
- New, innovative, higher value equipment



Price

- Different commercial models, different benefits
- Price-list comparison – is everything the same?



Global logistics

- Core coverage
- Allied partners to extend coverage



Key Takeaways

- 1 Equipment is on the critical path to initiation**
- 2 Complex studies = engage early**
- 3 Providers should add value with expertise**



Something to think on.....

70% of clinical trial delays are due to supply chain issues

How many could you avoid with stronger equipment partners?



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