



ALMAC

**Product Launch &
Commercial Supply
Models**

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Director, Commercial Services**



Journey to Product Launch Success with Almac

1 Framework

Regulatory framework & pathway for supply



2 Support

EU requirements for Qualified Person (QP) & Responsible Person (RP)



3 Readiness

New Product Introduction (NPI) – process design & development



3

Development to commercial

Transitioning from development to commercial drug product readiness (paediatric case study)



5

Launch & beyond

Understand varying launch and lifecycle models enabling you to select the perfect strategy for your product



Journey to Product Launch Success with Almac

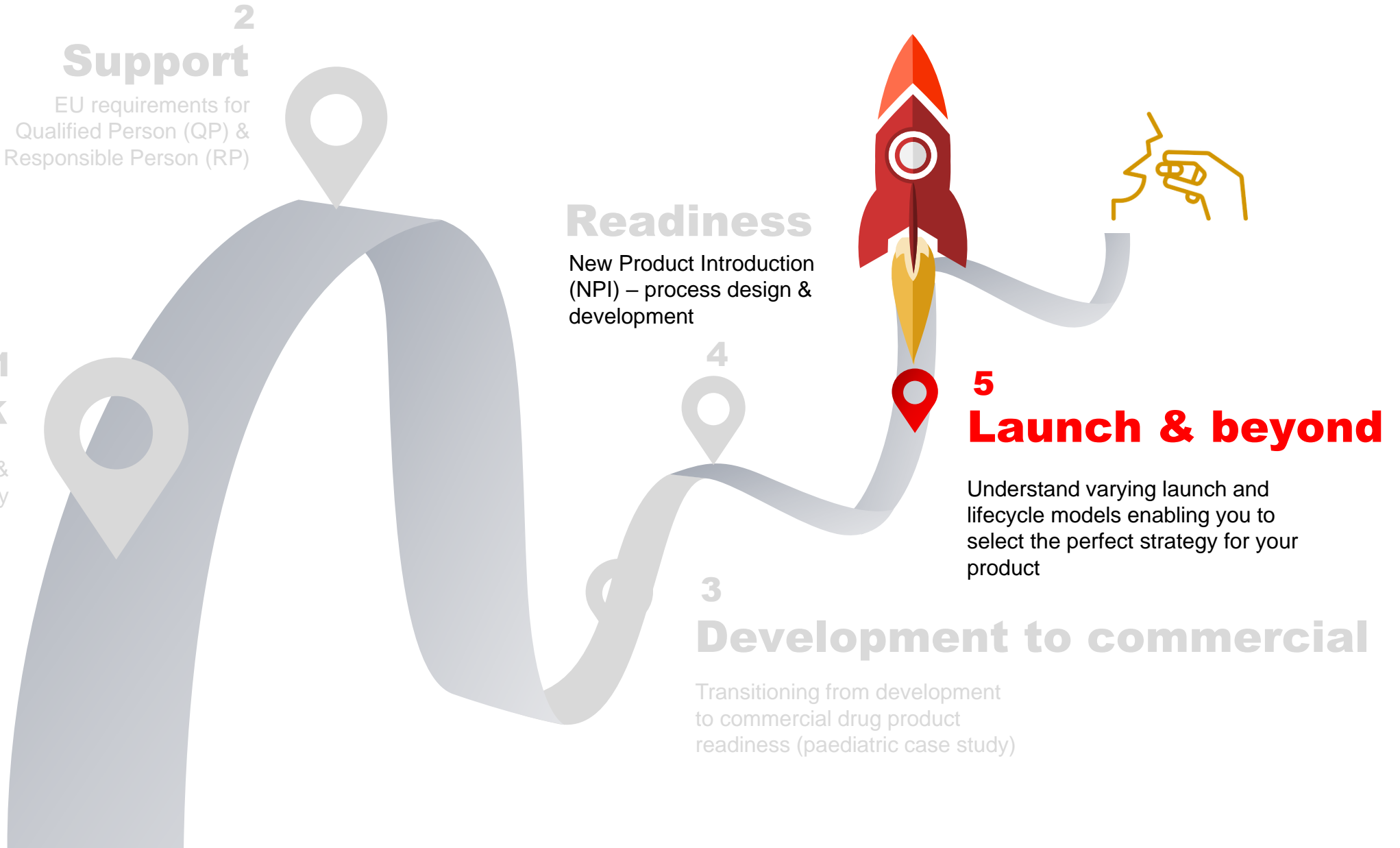
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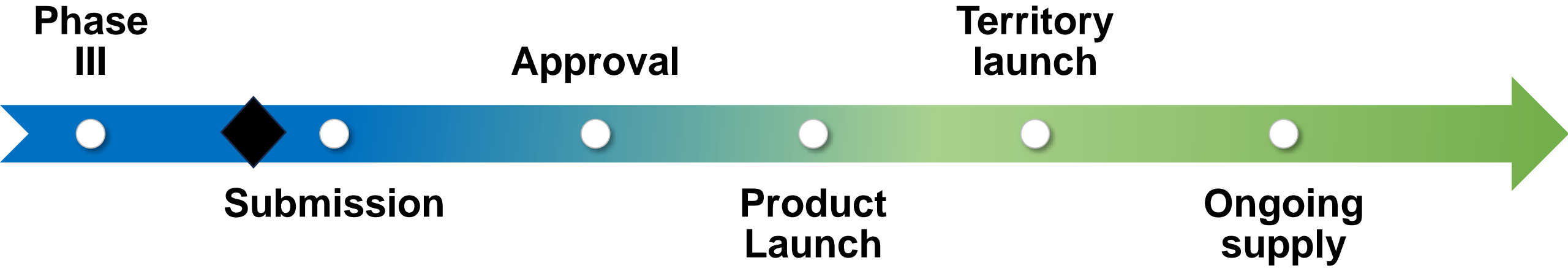
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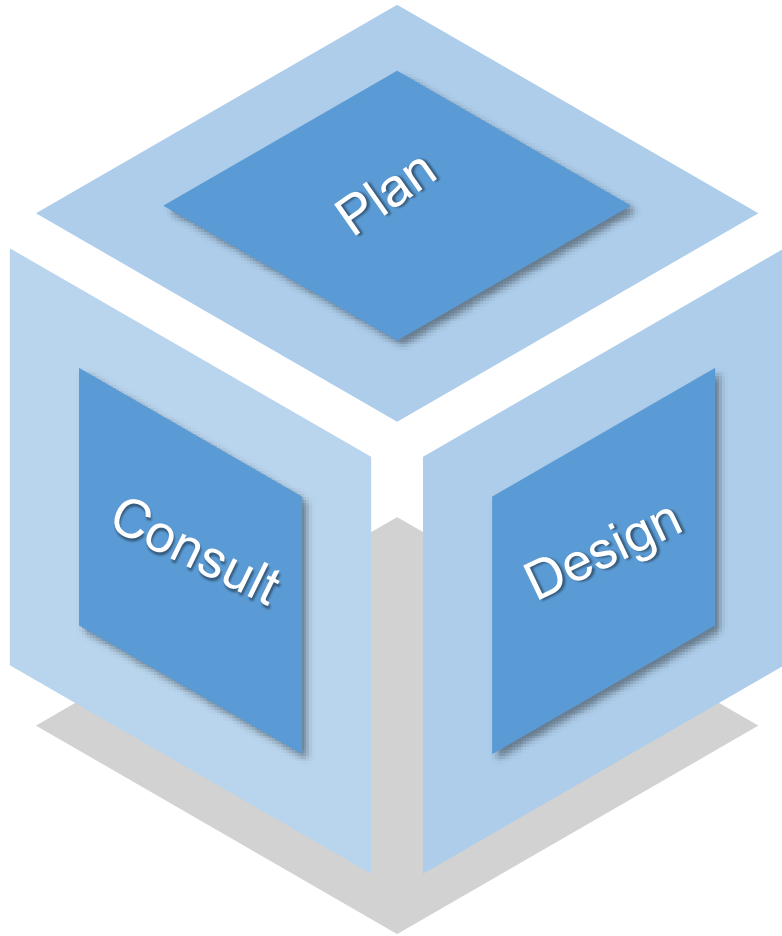
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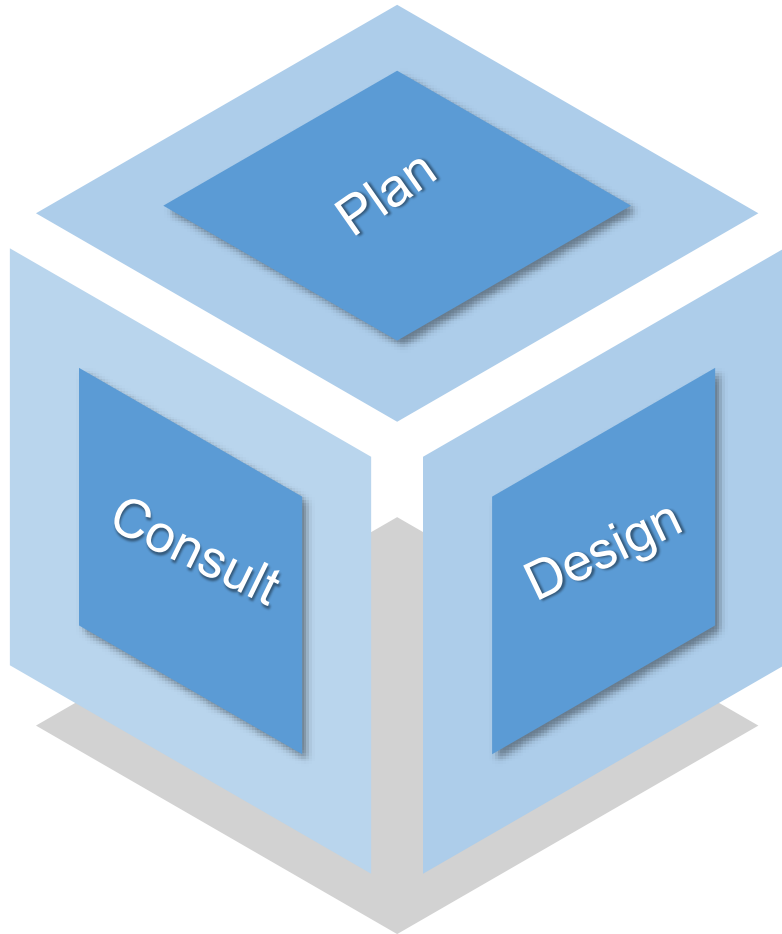
Planning for Product Launch & Commercial Supply



Planning for Product Launch & Commercial Supply



Planning for Product Launch & Commercial Supply



Launch model examples:

Standard launch

Expedited launch

Rapid launch

Supply model examples:

Standard supply

Enhanced supply

Premium supply

Just in Time (JiT) supply



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**Product Launch
Models**



Product Launch Planning – Model Selection

Phase III

Approval

Territory launch

Submission

Product Launch

Ongoing supply

Standard launch

Expedited launch

Rapid launch

Client considerations

What is your expectation of having stock in the market following approval?

90 days

30 days

20 hours

What is your approach to Risk (Cost)?

Low

Medium

High

Is packaging of product on critical path?

No

Yes

Yes

Product Launch Planning – Model Selection

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High

Is your packaging on critical path?

No

Yes

Yes

Client considerations

Component supply

Routine

Potential reserved capacity at print vendors

Reserved capacity at print vendors

Almac capacity, resource & consultancy

Routine planning

Reserved capacity & support

Dedicated capacity & support

Logistics partner

Routine

Potential stand-by service

Stand-by service

Tailored solutions

Launch Model - Scenarios

Client A - Agios

Rapid multi-SKU US launch



Planned to have product released within 4 days from PDUFA. Components would be printed once approval is received

Almac solution

- Mock launch performed 3 months prior to commercial Rapid Launch
 - Full “playbook” of plan, including production of mock packs
 - Tested printer capabilities to print & deliver PILs within 24 hours
 - Stock clock exercise to measure run times for each activity

Day	Time	Activity
0	19:15	PDUFA approval received
1	10:15	Artwork sent to print, component printing commenced
2	06:30	Printed components arrive at Almac
2	10:00	Production started
3	23:55	Production of 6 batches completed
4	15:30	6 batches QP released & dispatched from site

Launch Model - Scenarios

Client B

Expedited launch: IT, DE/AT

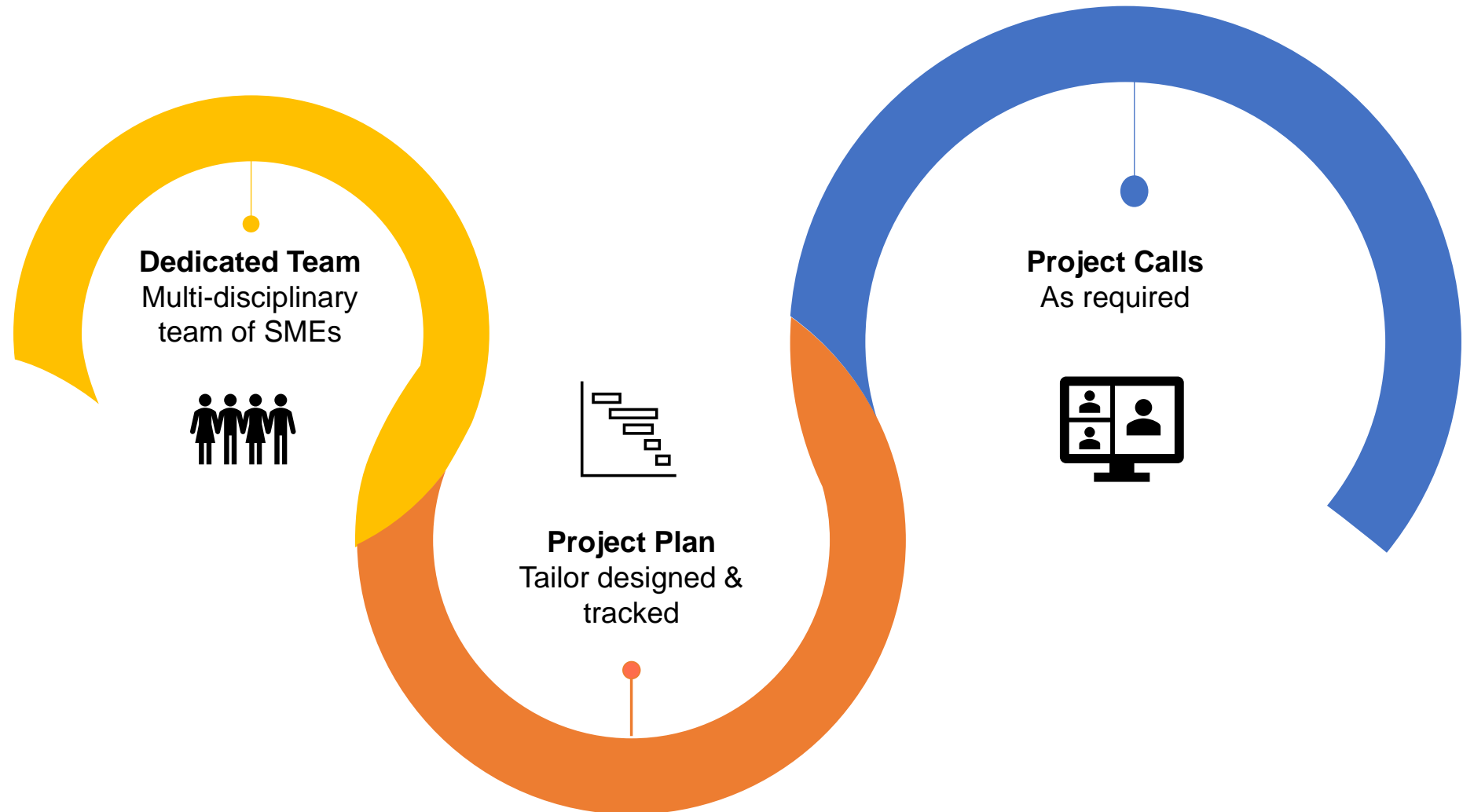
- Target timeline was product to be packed & released 1 month from approval.
- Planned to approve & print 2 sets of PIL artworks at risk ahead of regulatory approval.

Almac solution

- 2 sets of BOMs & Master Batch Records (MBRs) also drafted & reviewed
- Once MA approval granted, firm up on the appropriate PIL to use and circulate MBRs for approval.
- Commercial Launch batches were also to support the close out of the Process Validation.

Month	Activity
Aug 23	<ul style="list-style-type: none"> • Process Validation Batch 1 (non-commercial) • Commercial artworks approved
Sep 23	<ul style="list-style-type: none"> • Documentation (S&P, BOM, JP) Drafted & Reviewed • Commercial PSS's Approved • Commercial Packaging Components Ordered • QC inspection Commercial Components • Regulatory Approval
Oct 23	<ul style="list-style-type: none"> • Approve Batch documentation • Process Validation Batch 2 (commercial) & Launch Campaign • PV Protocol Approval • Packaging Process Release • QP Partial Release
Nov 23	<ul style="list-style-type: none"> • Dispatch x3 SKUs

Product Launch - Execution



Product Launch – Success!!

Almac takes pride in celebrating our clients' Product Launch success together to acknowledge the effort, dedication and professionalism of our employees and the relationships with our clients.

A lot of effort and collaboration goes into managing Product Launches from all involved, sometimes out of hours.



As part of our continuous improvement approach within Almac Pharma Services, we also conduct a “lessons learned” session with all involved to support optimisation of the process for future launches.



ALMAC

**Commercial Supply
Models**



Commercial Supply Models

Phase III

Approval

Territory launch

Submission

Product Launch

Ongoing supply

Standard supply

Enhanced supply

Premium supply

JiT supply

Client considerations

What is your required order lead-time?

90 days+

60 days

30 days

20 - 48 hours

How predictable and stable is your demand (forecast)?

Steady / predictable

Fluctuating

Fluctuating

Personalized medicine

Any restrictions on bulk availability for supply?

Readily available

Challenging

Restrictive

Restrictive

What Residual shelf life will product have remaining on release to market?

Standard

Standard

Short

Short

Commercial Supply Models

Phase III

Approval

Territory launch

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Product Launch

Ongoing supply

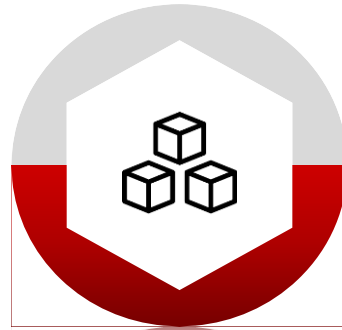
		Standard supply	Enhanced supply	Premium supply	JiT supply
Client considerations	What is your required order lead-time?	90 days+	60 days	30 days	20 - 48 hours
	How predictable and stable is your demand (forecast)?	Steady / predictable	Fluctuating	Fluctuating	Personalized medicine
	Any restrictions on bulk availability for supply?	Readily available	Challenging	Restrictive	Restrictive
	What Residual shelf life will product have remaining on release to market?	Standard	Standard	Short	Short
Tailored solutions	Almac capacity & resource	Routine	Routine (low volume) Reserved (high volume)	Reserved	Dedicated
	Supply management	Order driven	Forecast driven	Forecast driven	Forecast driven
	Component supply	Purchased on receipt of PO	Purchased to forecast	Components on site	Components on site & fully released

Client A – Multi Product Supply



6

Products



10

Unit Processing Operations
(Manufacture & Pack)



3

Almac Sites Utilised



994,631

Units Delivered 2022

Supply needs

- Fluctuations in market demand & multiple launches for additional paediatric populations.
- Need maximum flexibility to react to changes in demand at short notice and to prioritise running order to meet demand / launches.

Almac solution

- Achieved through dedicated equipment and processing rooms, shared assets with reserved capacity model & dedicated project team (e.g. project management, analytical, QA, validation)

Client B – Gene Therapy Product



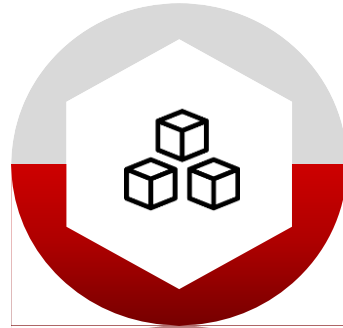
16

Market SKUs



37

Patient Weight Variations



592

Total Potential SKUs



-80°C

Product Temperature



>1,291

Batches processed &
QP released with 100% OTIF

Supply needs

- Personalised patient packs. (one pack per patient)
- Orders placed on patient weight (vials per pack)
 - Product to be delivered & infused in a quick timeframe before patient weight changes.
- Ultra Low Temperature controlled product (-80oC)

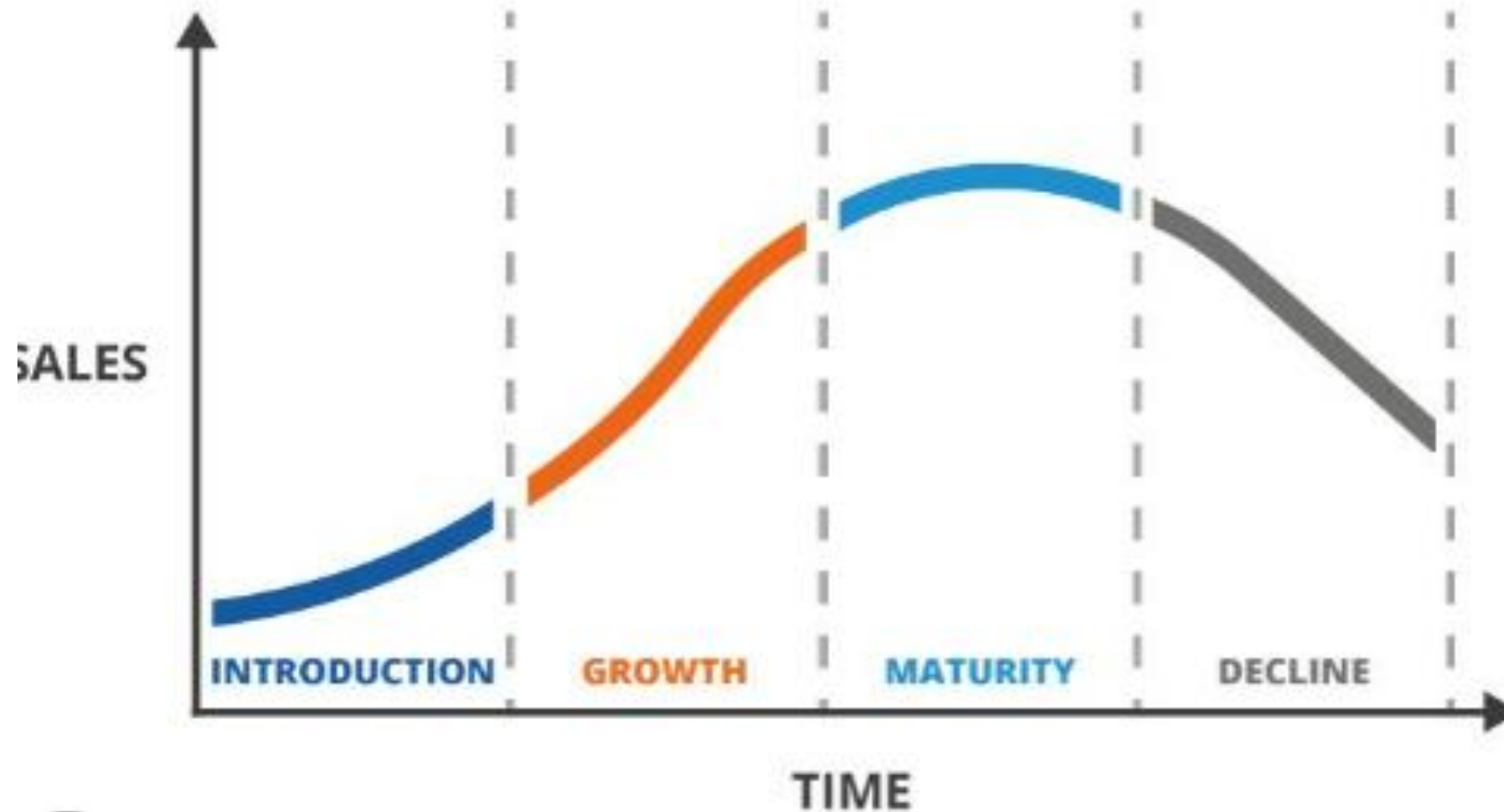
Almac solution

- 48 hour lead time from PO receipt QP Release
 - Agreed expedite process for 24 hour lead time
- Dedicated ULT processing room, freezers & operational resource
- Dedicated project team for project management and batch release:
 - Out of Hours & weekend cover available on request
 - Daily Order & Forecast review meetings

Commercial Supply Models

Your commercial supply model may need to change through the life cycle of your product

PRODUCT LIFE CYCLE



Commercial Supply Model - Scenarios

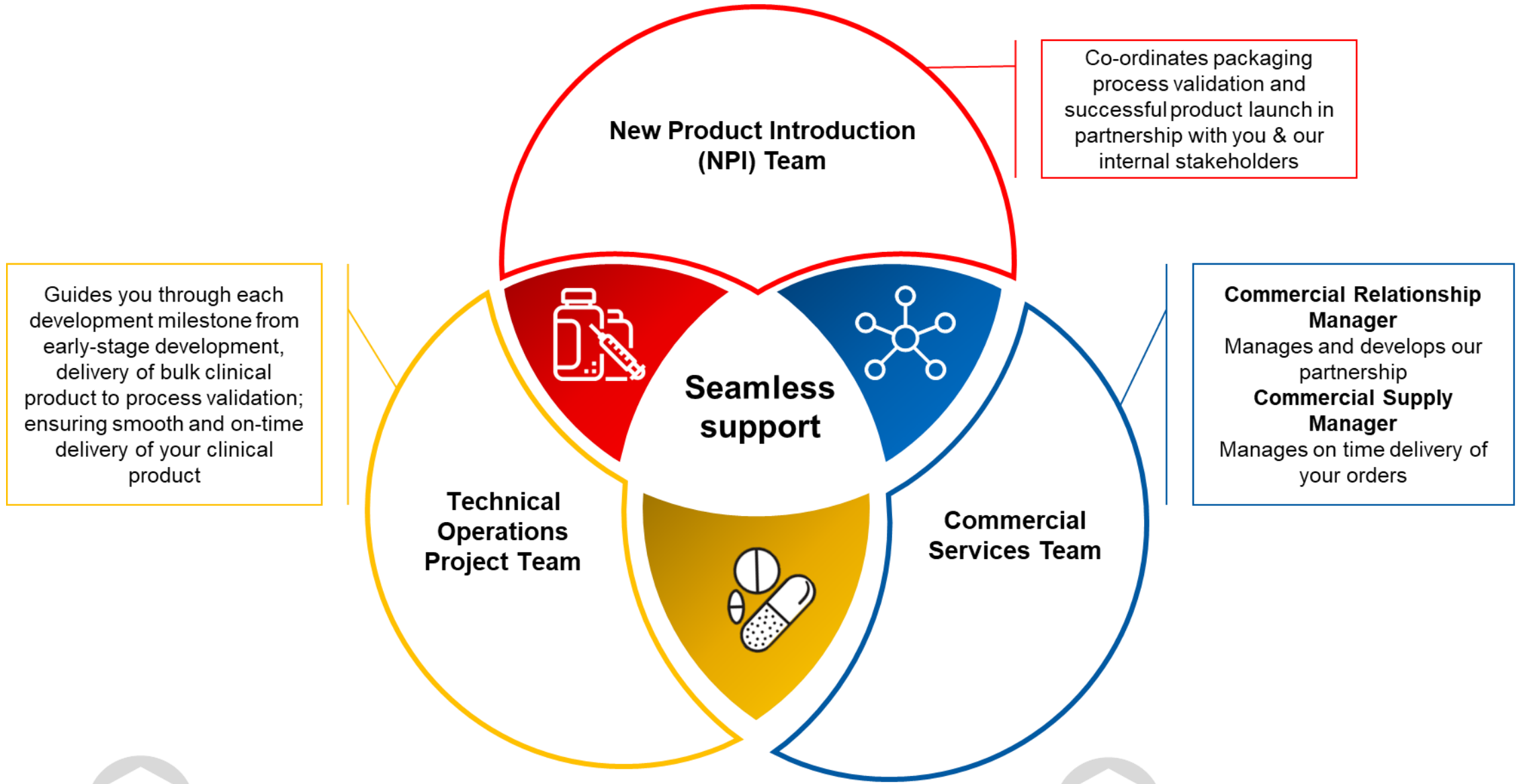
A	B	C
<p>Client introduced China market which increased demand by 100%.</p> <p>Supply unable to maintain stock in markets due to API capacity.</p>	<p>Client experienced media fill issue at DP filling site leading to significant delays to DP supply.</p> <p>Expected to be close to stock outs in most markets for next 12 months.</p>	<p>Client's product acquired by large Pharma company which has launched rapidly into many new markets</p> <p>Demand outweighing supply of DP vials.</p>
<p>Almac solution</p>		
<p>Reduced lead time from 90 days to 30 days</p>	<p>Reduced lead time from 60 days to >30 days</p>	<p>Reduced lead time from 90 days to 30 days</p>



**Commercial Supply
Delivery**



Transition from NPI to Commercial



Expert project teams assigned relative to your project

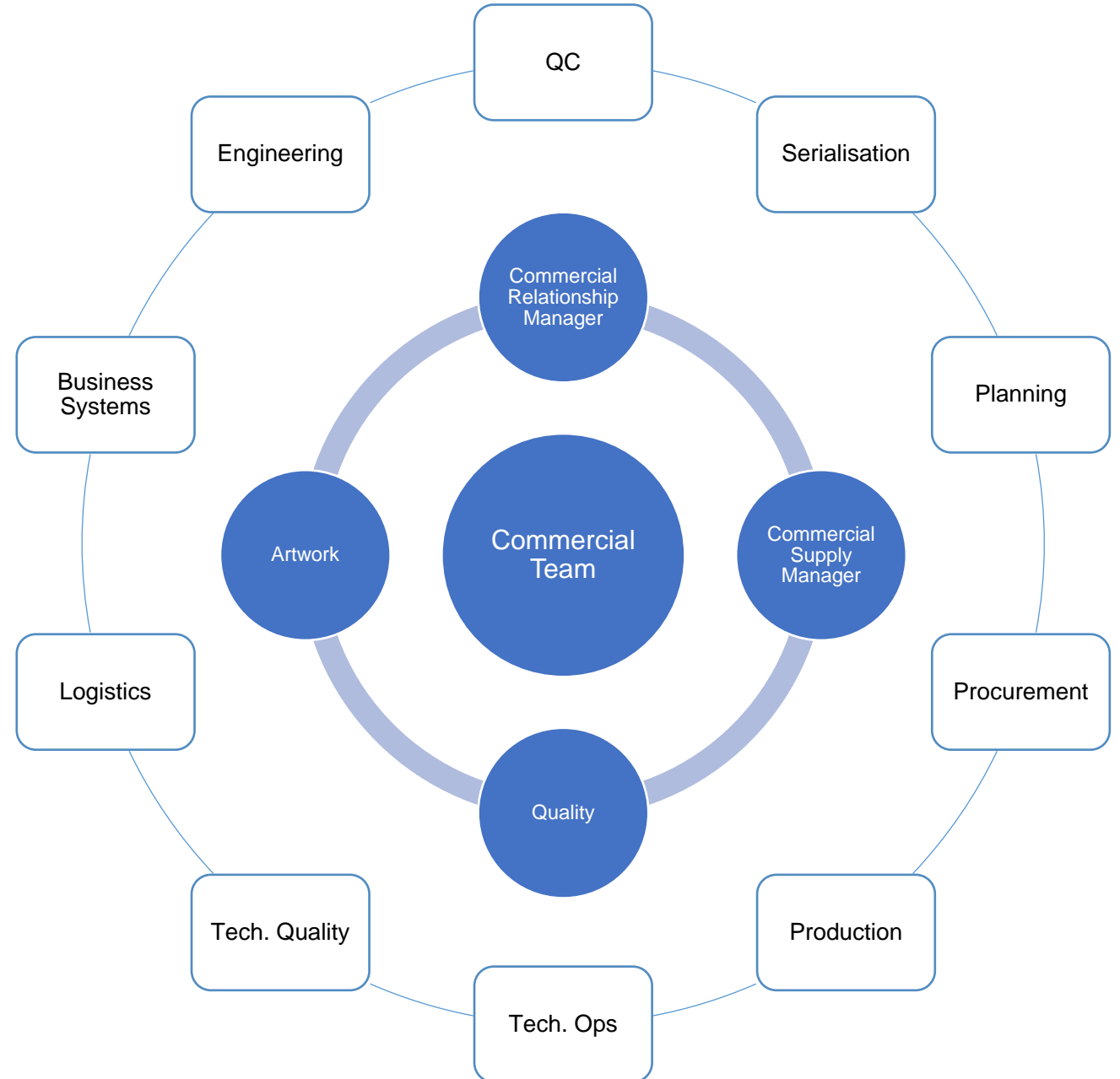


Dedicated point of contact

Commercial Supply Team

Dedicated product team responsible for:

- On Time in Full (OTIF) Supply of Product
- Managing new SKU launches
- Artwork Changes
- New scopes of work (new pack format etc.)
- Commercial Relationship
- Reporting & KPIs
- Quality oversight



Governance Models

We work together to develop an appropriate Governance Model ensuring full oversight of performance & our relationship



KPIs & Metrics

In order to ensure transparency and oversight, Almac records and presents KPIs & metrics at our Business Review Meetings

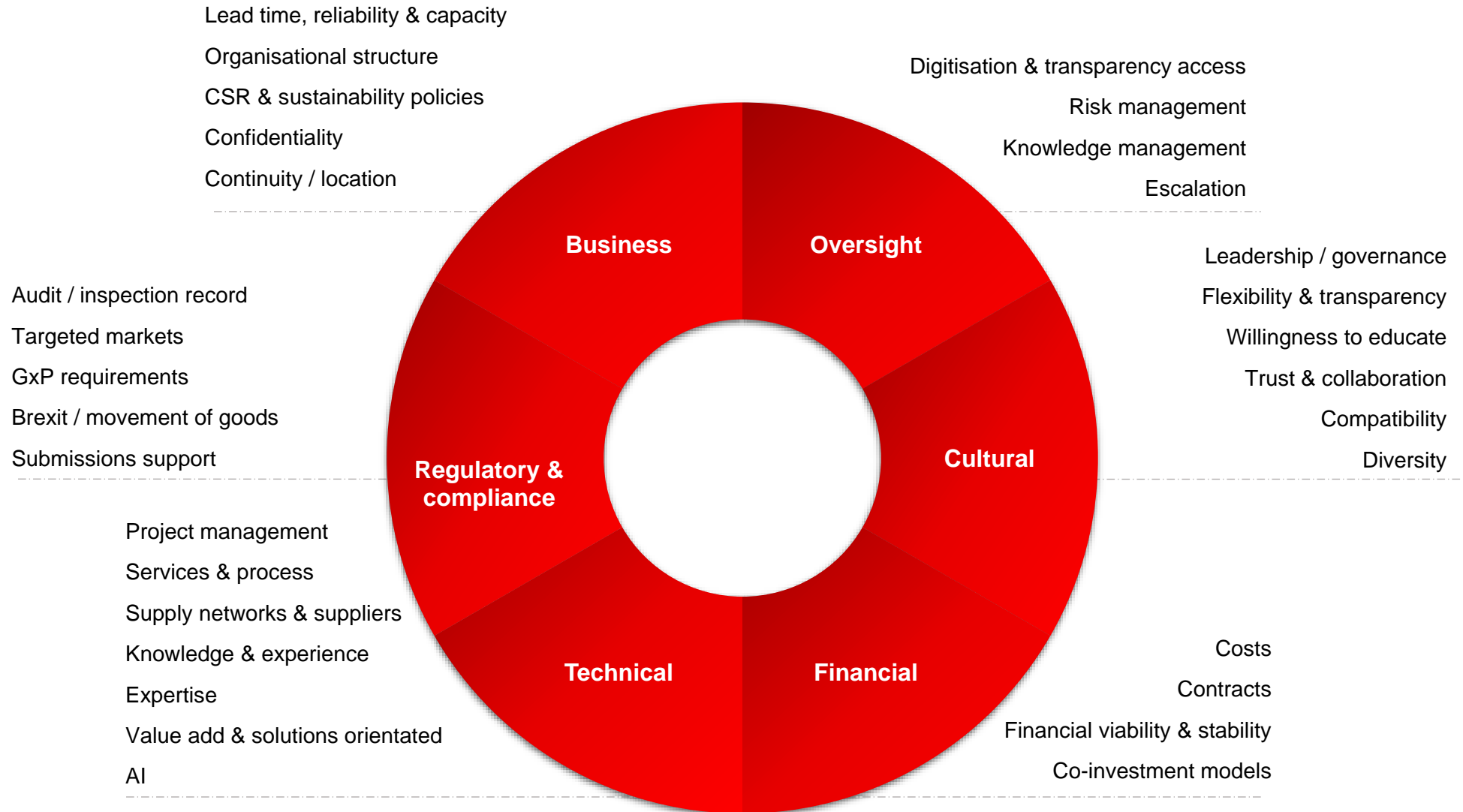
Deviations:	Raised: 0 (Closed: 0 Open: 0)	Compliance
Deviations Critical/Major rate	NMT 20% of deviations are classified as critical/major (by QA)	0
Deviations logged on time	NLT 80% of deviations will be logged within 1 working day of discovery	100%
Deviations rate per batch	NMT 10% of deviations logged per batch records produced	e.g 5%
Deviations closed on time	NLT 80% of deviations closed on time	100%
Change Requests:	Raised: 0 (Closed: 0, Open: 0)	Compliance
Change Requests Temporary	NMT 50% of changes identified as temporary	e.g 10%
Change Requests (non-effective)	NMT 10% of major changes deemed as non-effective	e.g 5%
Change Requests closed on time	NLT 80% of Change Requests closed on time	e.g 90%
Product Complaints	Raised: 0 (Closed: 0, Open: 0)	Compliance
Product Complaints closed on time	NLT 80% of product complaints closed on time	e.g 90%
Vendor Queries/Complaints	Raised: 0 (Closed: 0, Open: 0)	Compliance
Vendor Queries/Complaints closed on time	NLT 80% of vendor queries/complaints closed on time	e.g 90%

Quality metrics

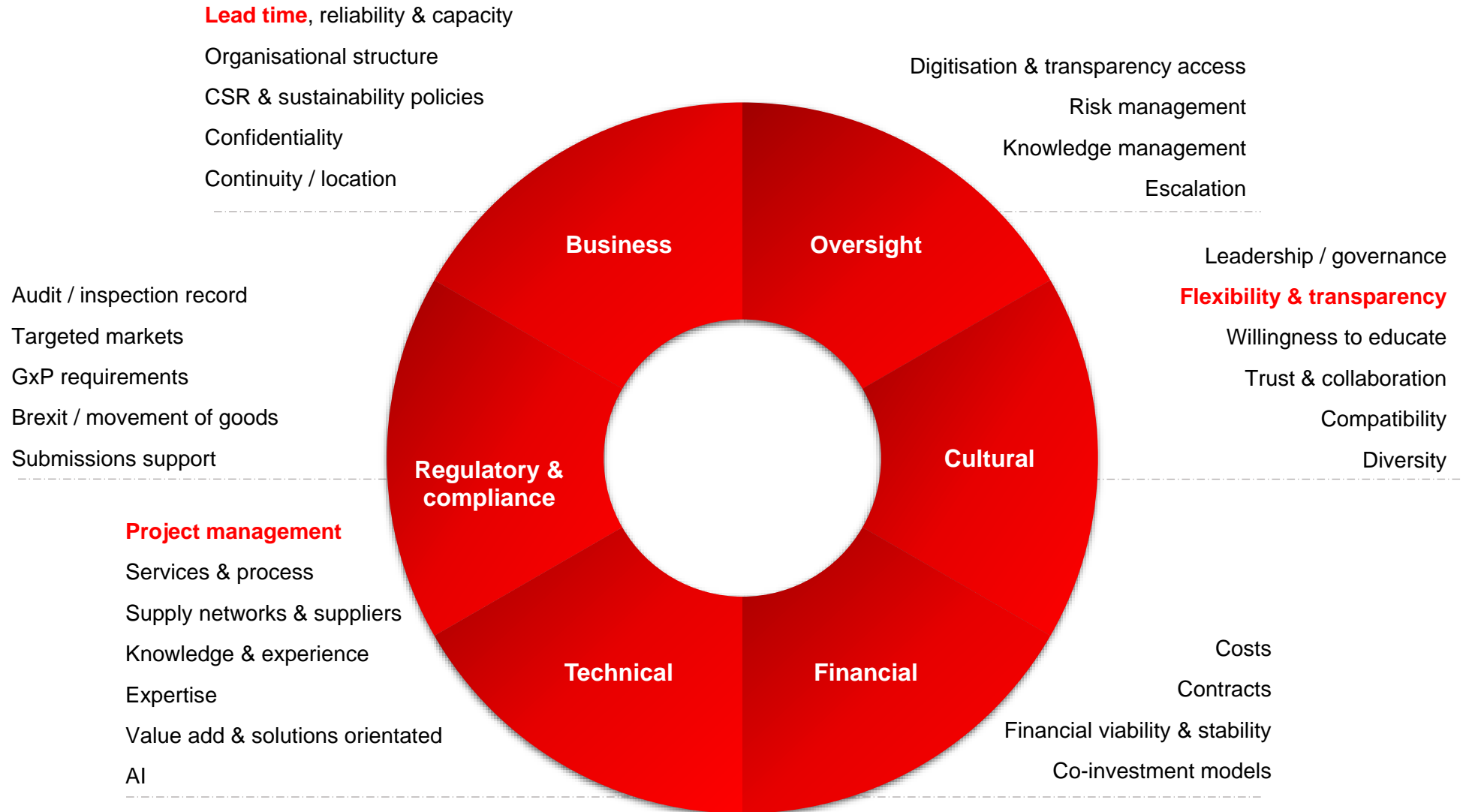


On Time In Full

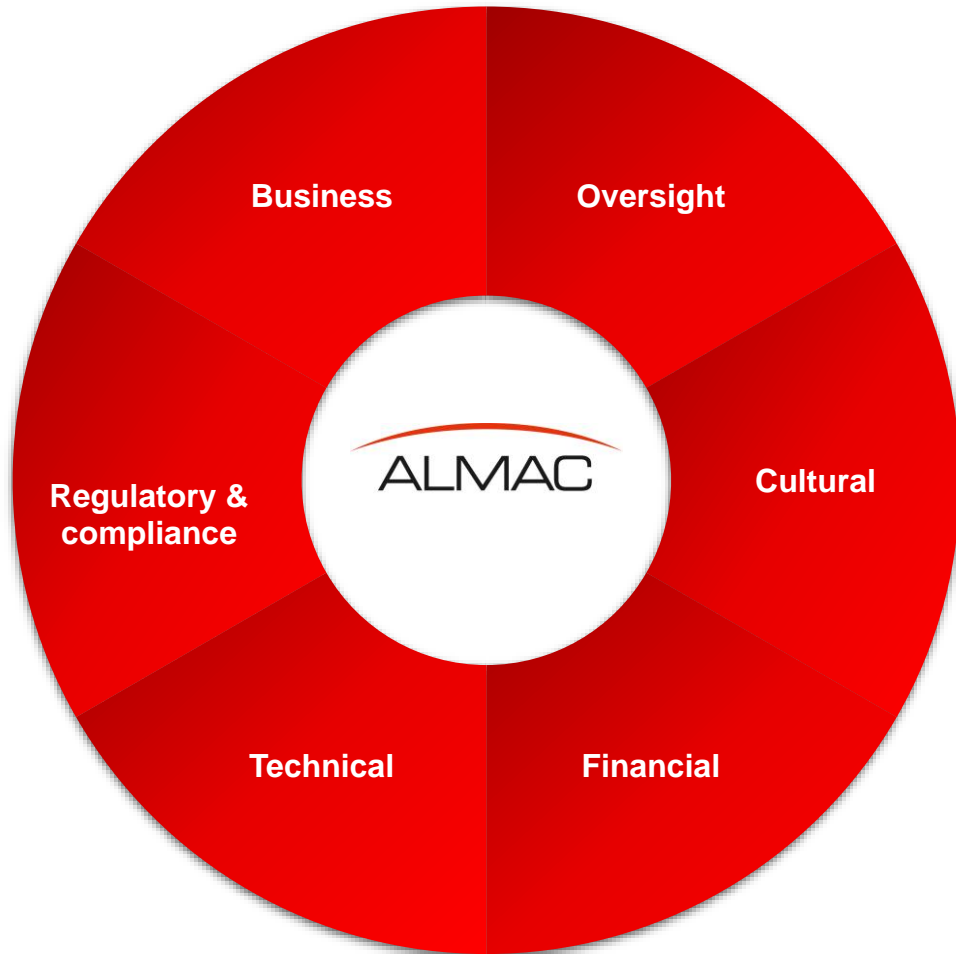
Commercial Supply – your considerations



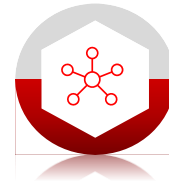
Commercial Supply – your considerations



Commercial Supply – tailored solutions



Stability



Flexibility



Partnership

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