



Commercial Considerations for Planning a Successful Cell and Gene Therapy Product Launch

October 14, 2019



Clinical Trial

- Compliance with GMP, GCP, GDP standards and local regulations.
- Importation and QP Release services
- Licensure for clinical trials
- Regulatory Expertise
- Translation Services
- High degree of flexibility due to low volumes
- Guiding and supporting CGT clients
- Additional services: analytical, formulation, primary/secondary packaging IRT to distribution (incl. DTP)
- Randomization and blinding capabilities
- Comparator sourcing

A flawless transition from Clinical to Commercial in essential for success

VS

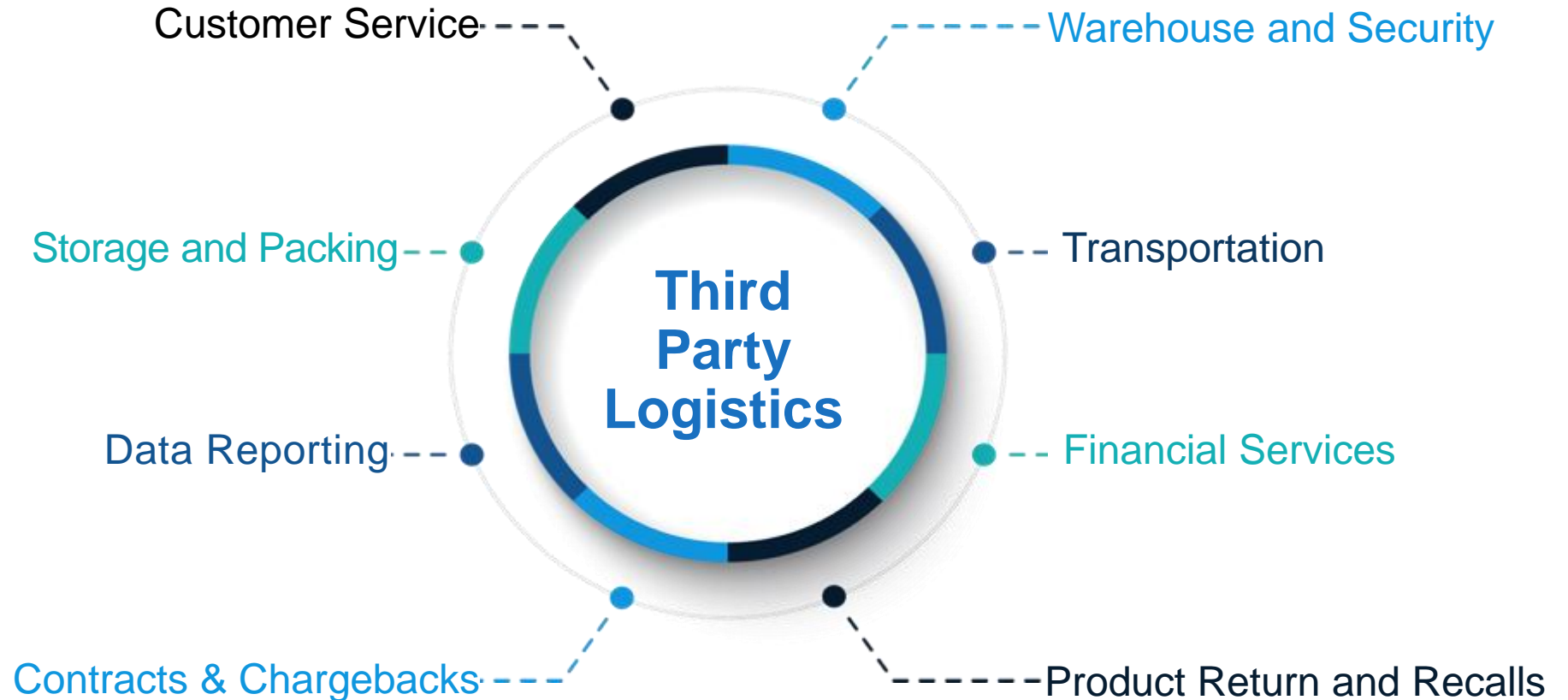
Commercial Therapy

- Board of Pharmacy License required across the US
- Third Party Logistics Provider
- Compendia listing
- Fair Market Value Assessment for fees paid to all commercial vendors (OIG regulatory concern with civil and monetary penalties)
- Commercial Distribution Agreement
- Direct Hospital Agreements
- Customized Data Sets for unique ID's
- Patient Services (internal or external) including Reimbursement, Patient Assistance Plan, Co Pay Solution, Patient and Care Giver Travel Arrangements, Foundation Support, etc...
- Product Return Policy

Standard 3PL Offerings

Third Party Logistics (3PL)

is the function by which the owner of goods outsources various elements of the supply chain to one 3PL company that can perform the management function of the client's inbound freight, customs, warehousing, order fulfilment, distribution, and outbound freight to the client's customers

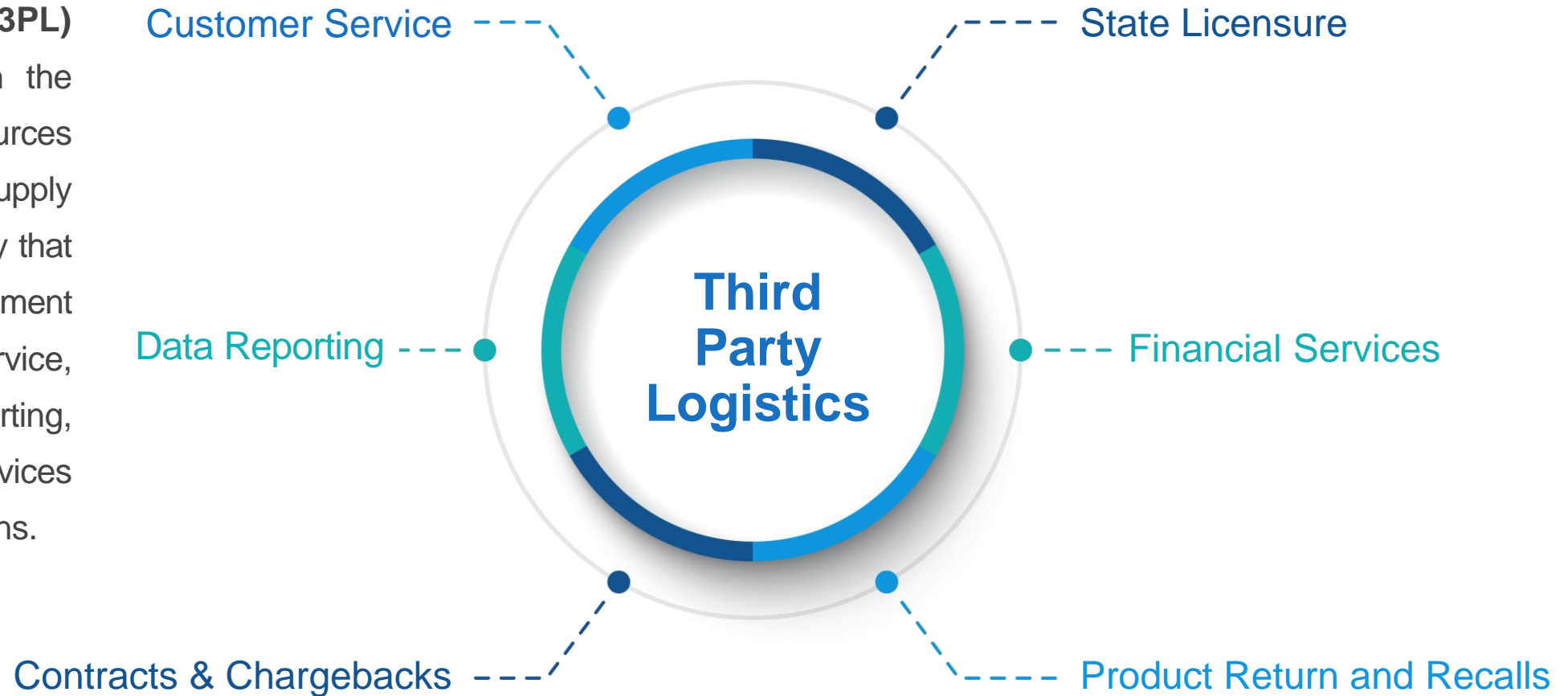


Add on services to support the full lifecycle are often available:
Serialization, samples, marketing materials, repackaging/relabeling.

Cell and Gene 3PL Needs

Third Party Logistics (3PL)

is the function by which the owner of goods outsources various elements of the supply chain to one 3PL company that can perform the management function of customer service, state licensure, data reporting, financial back office services and potential product returns.



Add on services to support the full lifecycle are often available:
Serialization, marketing materials.

Cell and Gene 3PL Details at-a-Glance

Customer Service Dedicated customer service team that understands the cell and gene space

State Licensure Manufacturer will need a state licensure solution

Financial Services Invoicing and Collections Management processed and put into a reporting system

Contracts, Chargebacks Government contract pricing, 340b

Data Reporting Flexible, customized reporting options with dedicated portal that can handle cell and gene requirements

Reverse Logistics Optimize return strategies leveraging 3PL expertise

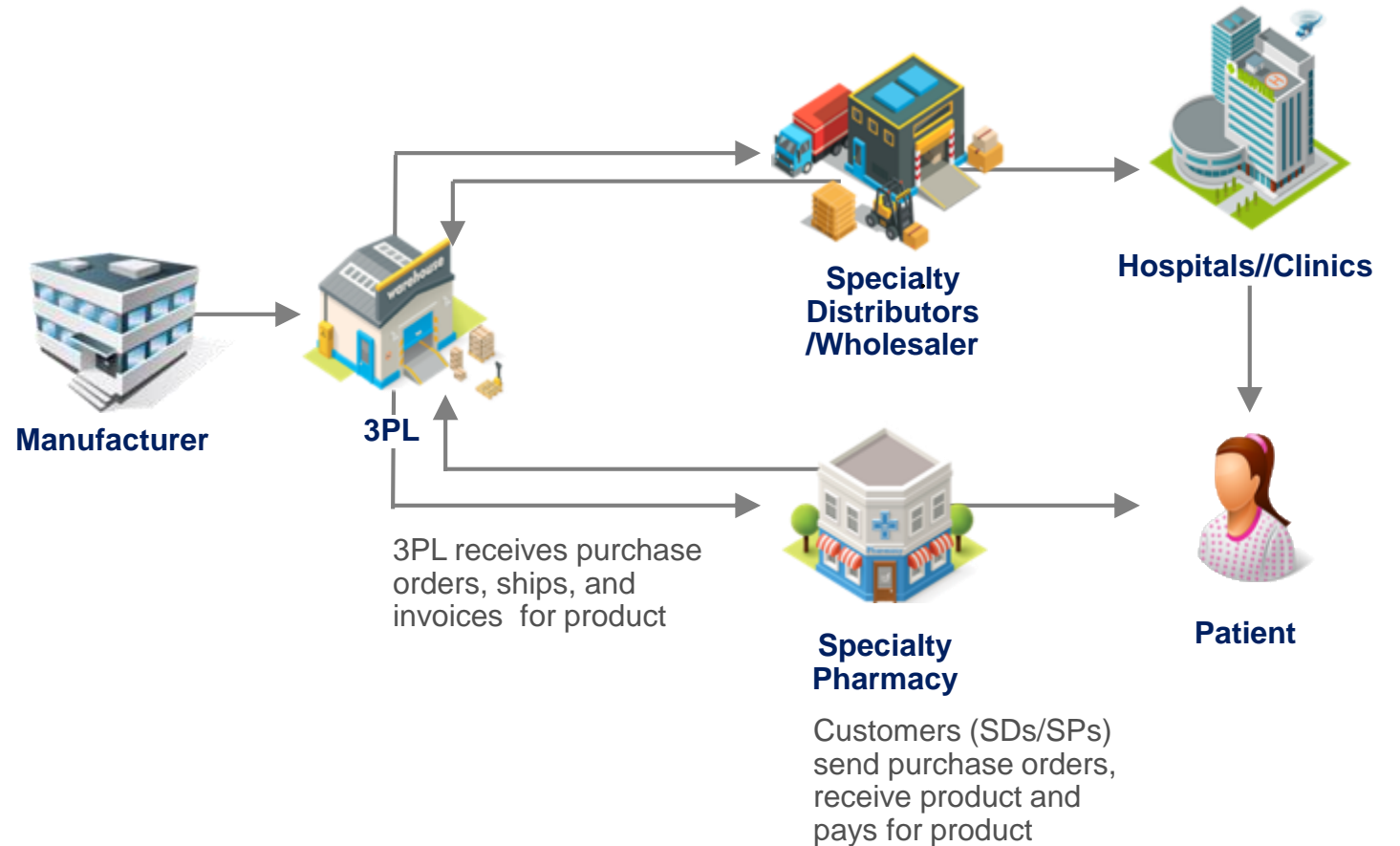
What Makes a Good 3PL Partner?

- Value
- Proper Accreditations
- Account Management within/across all stakeholders
- Account Management to the manufacturer partner
- Array of affiliated services
- Customer Service Systems
- Familiarity in the space
- Data Portal
- SOC compliant financial reporting

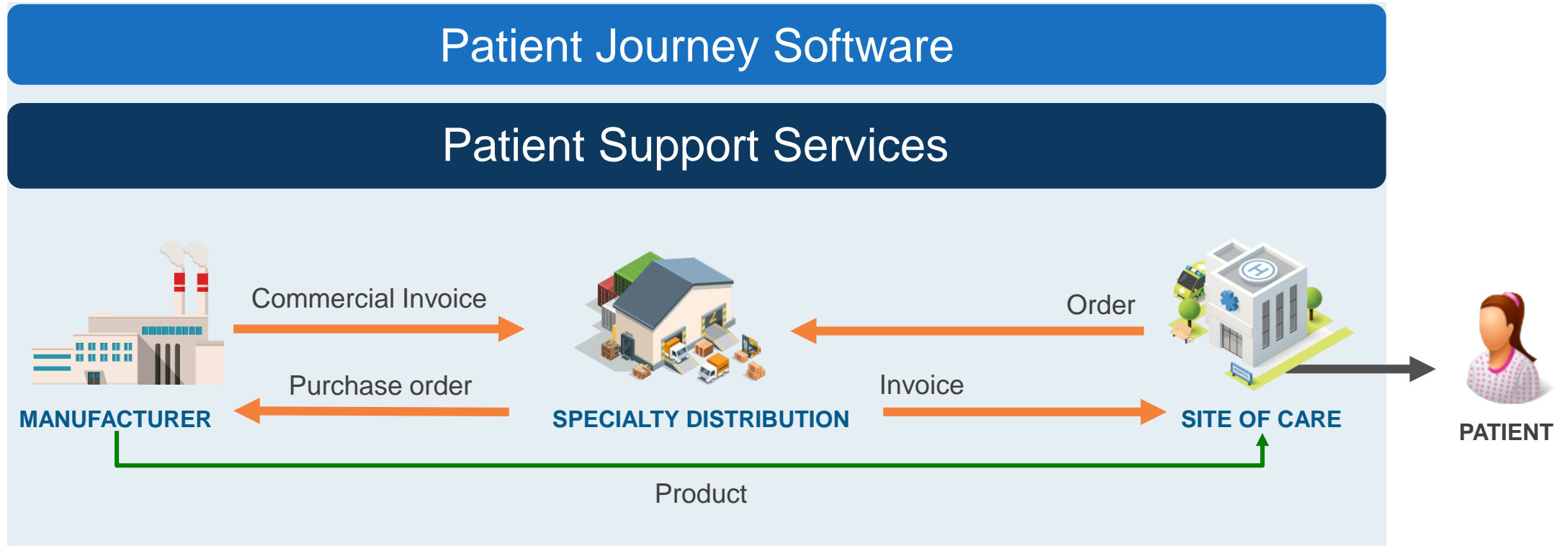


Typical 3PL and Distributor Flow

1. Manufacturer sends inventory to 3PL
2. Upon Manufacturer work orders, 3PL releases and stocks product in distribution center
3. Customers place their orders with 3PL via EDI
4. 3PL processes orders - picks, packs, and ships product to customers (SD's/Wholesalers/SP's)
5. Title transfers when product is received by SDs/Wholesalers/SP's – FOB (freight on board) Destination
6. 3PL invoices SD's/Wholesalers/SP's based on Manufacturer negotiated terms
7. Money is deposited into a lock box owned by Manufacturer
8. 3PL monitors the process on behalf of Manufacturer per work orders from Manufacturer

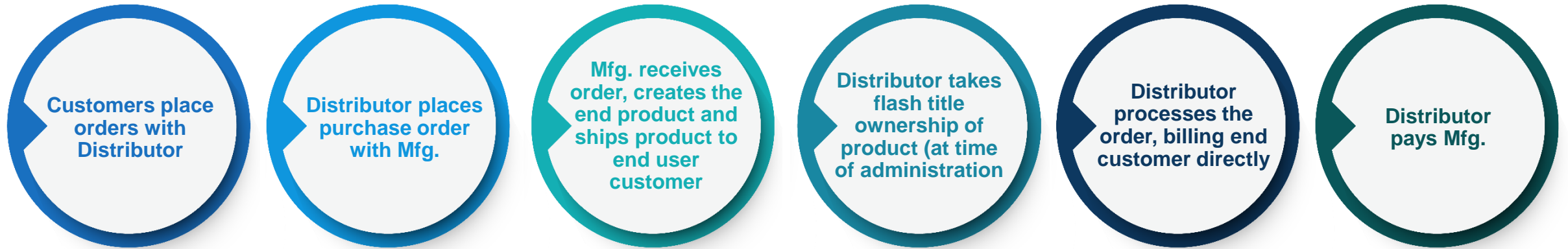


Flash Title Flow



1. Hospital Places the order with the manufacturer with the appropriate data
2. Manufacturer places order with Distributor with the appropriate data
3. Distributor cuts a Purchase Order and sends it to Hospital / Product is shipped from the manufacturer directly to the hospital
4. Hospital pays the distributor
5. The distributor pays the manufacturers 3PL (who collects the money on behalf of the 3pl)

Flash Title Model Steps



Model Benefits

- Maintains Customer Ecosystem
- Provides a common experience for all stakeholders
- Customers have visibility to products within existing ordering platforms
- Minimal risk leveraging existing distribution infrastructure

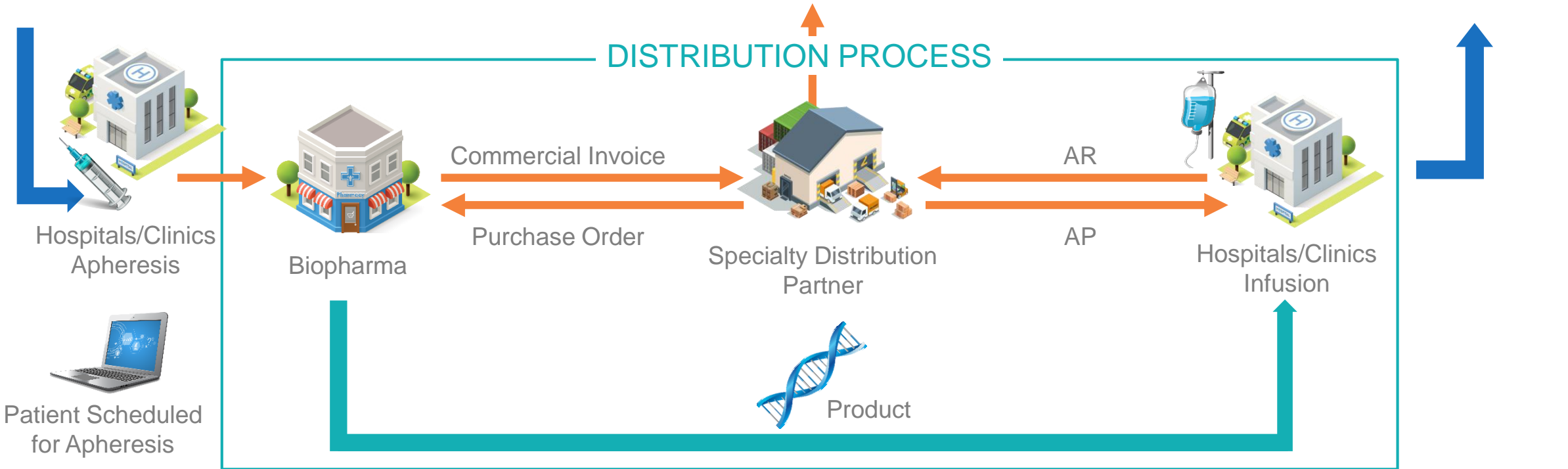
CAR T Service Ecosystem

HUB SERVICES



Patient Access & Coverage

Patient Adherence & Monitoring



Patient Management Software (Chain Of Identity/ Chain Of Custody)

Flash Title Providers

SERVICE	EXPRESSSCRIPTS/CIGNA	AMERISOURCE BERGEN	CARDINAL HEALTH	MCKESSON
Primary Business	PBM/Payer	Wholesaler	Wholesaler	Wholesaler
3PL	CuraScript	ICS	Cardinal 3PL Services	Rx Crossroads
Flash Title	yes	yes	yes	yes
Specialty Distributor	CuraScript	ICS Direct/ASD	Cardinal Specialty	McKesson Specialty Health
Specialty Pharmacy	Accredo	US Bio	Co promote with PantherRX	Biologics
HUB/Patient Services	Accredo Dedicated UltraOrphan TRC	Lash Group	Sonexus	Rx Crossroads
Alternative Models	Yes	Not Yet	Yes	Not Yet
Commitment to the Space	Yes	Yes	Yes	Yes
Cell and Gene Experience	Yes	Yes	Yes	Prelaunch

What Makes a Good Flash Title Partner?

- Proper Accreditations
- Partner needs to be cost effective, scalable and flexible to integrate with appropriate stakeholders
- 100% dedicated, hi touch, hi tech customer service
- Successful experience with flash title
- Ability to customize the program and be able to adjust at any given time
- Quality of Service – hours, turn around times, responsiveness
- Ability to customize data to the cell and gene space requirements
- Best in class account management



The Role of Specialty Pharmacy

- Specialty Pharmacies are aggressively targeting the market
- Excellent experience with complex disease states and patient management
- Creative, innovative solutions
- Potentially eliminate Buy and Bill from hospitals
- Pre and Post treatment opportunity
- The opportunity to identify patients
- Actively working with State Boards to find Solution for Cell and Gene Therapies : Drive by Model, Locate a Pharmacist in the manufacturer's facility, Is a photo of the product ok....and more
- Clinic space offers significant opportunity



Critical Areas for Hub Support



Overall Case Manager Responsibilities

- Care coordination across all stakeholders to ensure the patient has an excellent experience
- Reduce Hospital administrative burden
- Reimbursement support for pharmacy and medical benefit therapies

Hospital Touch Points	Patient Touch Points	MFTG Touch Points Points
<ul style="list-style-type: none">• Overall Traffic Navigator• Pre and Post Patient Management• Rapid Benefits Investigation (BI) and Prior Authorization (PA) support and appeals management• REMS enrollment• Triage to product billing to Specialty Pharmacy• Hospital Accreditation Support	<ul style="list-style-type: none">• Financial Prescreening & Counseling• Copay assistance• PAP• Drug education• Emotional supportive care• Travel coordination for the patient and caregiver• Post-needle, at-home management• REMS management	<ul style="list-style-type: none">• Overall Traffic Navigator• Customized data from the HUB• HUB acts as an agent of the manufacturer• Copay assistance for patient• Delivery coordination with Hospital and Patient• Ability to enforce program requirements



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