



Cell & Gene Supply Chain

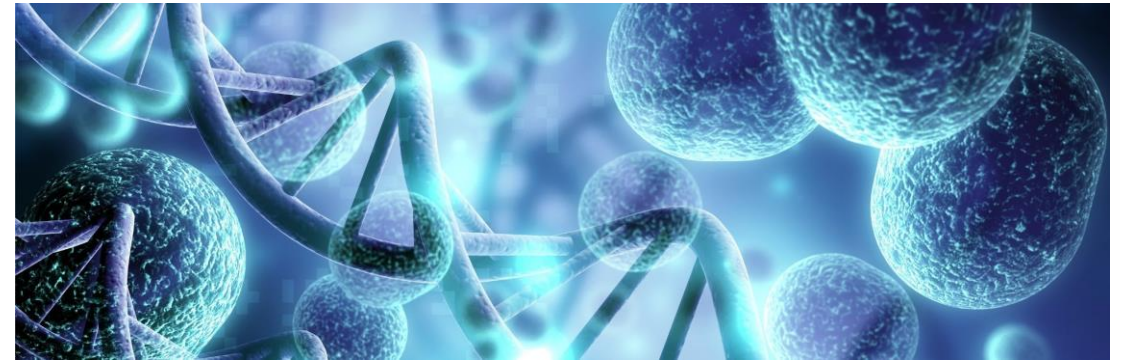
OVERCOME CHALLENGES AND CREATING A SUSTAINABLE SUPPLY CHAIN



Agenda

Topics

- **Helicopter view C/G Landscape**
 - **ATMP's**
 - **Figures**



Landscape

ATMP's

Janssen invests in European production site for cell Belgium

Janssen will produce innovative cell therapies in Belgium. The Tech Lane Science Park in Ghent will be the location of Janssen's first European state-of-the-art facilities for the production of CAR-T therapy. The facilities are being developed in cooperation with Legend Biotech to enable the future production



Roche To Buy Spark Therapeutics For \$4.8B

Swiss drug maker Roche entered into a definitive agreement Monday to acquire Philadelphia gene therapy pioneer Spark Therapeutics in an all-cash deal valued at \$4.8B.



CAR-T cell therapy specialist Kite Pharma, now part of Gilead Sciences, has expanded its cell therapy manufacturing footprint in Europe. A 117,000 square-foot facility in Hoofddorp, the Netherlands, will be operational by 2020.

Kite's CD19-targeting CAR-T cell therapy **axicabtagene ciloleucel**, which received FDA

BMS to invest in new cell therapy manufacturing site in Europe

23rd April 2021



Bayer plots \$1.6B investment at German pharma manufacturing sites, with digital transformation a key

Novartis constructing \$92m CAR-T plant as Kymriah arrives in EU

by [Dan Stanton](#)
Tuesday, August 28, 2018 12:00 pm

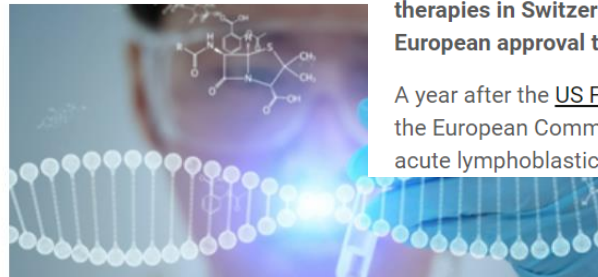
Up to 450 jobs will be created as Novartis commits to a production site for cell and gene therapies in Switzerland. The investment will support CAR-T drug Kymriah, which received European approval this week.

A year after the US Food and Drug Administration (FDA) approved Kymriah (tisagenlecleucel), the European Commission (EC) has granted the Novartis' therapy approval to treat B-cell acute lymphoblastic leukemia (ALL).

Cell & Gene Therapy Investment Outlook In 2021

By Steve Kemler and Adam Lohr, RSM

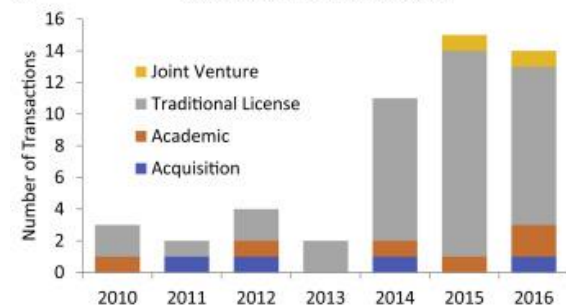
Cell and gene therapies are one of the most active areas of research and investment in the development of medicine. The appeal is understandable given the promise of novel drugs targeting poorly treated diseases; the recent success of several new gene and cell therapies; and substantial capital flowing in from private



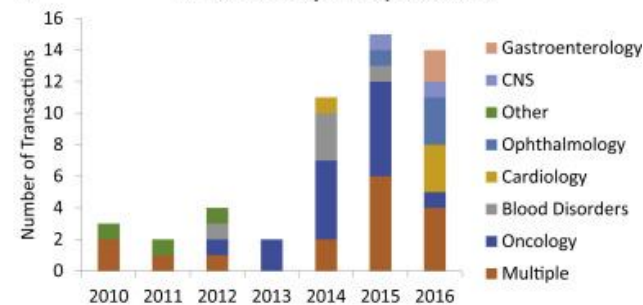
Landscape

Figures

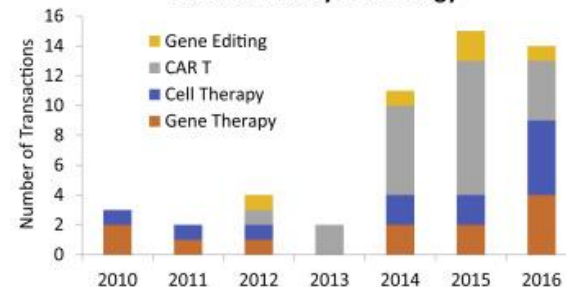
A Nature of the Transactions



B Transactions by Therapeutic Area



C Transactions by Technology



D Top Entities By Number of Transactions

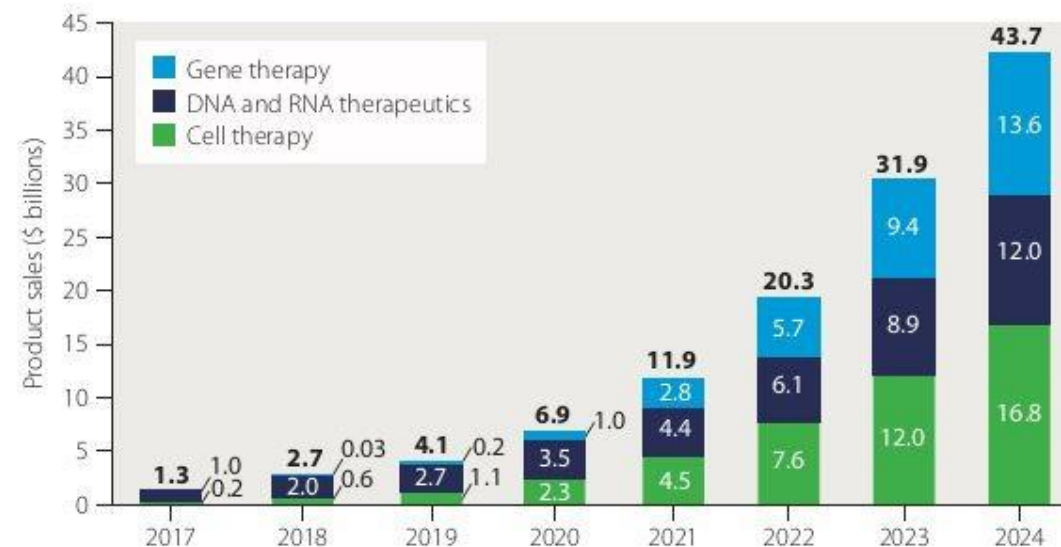
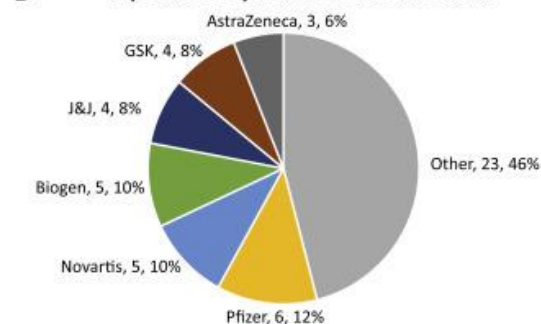


Fig. 1 | Sales growth trends of cell, gene and nucleic acid therapy products from 2017 to 2024. Source: EvaluatePharma, March 2019.

Past

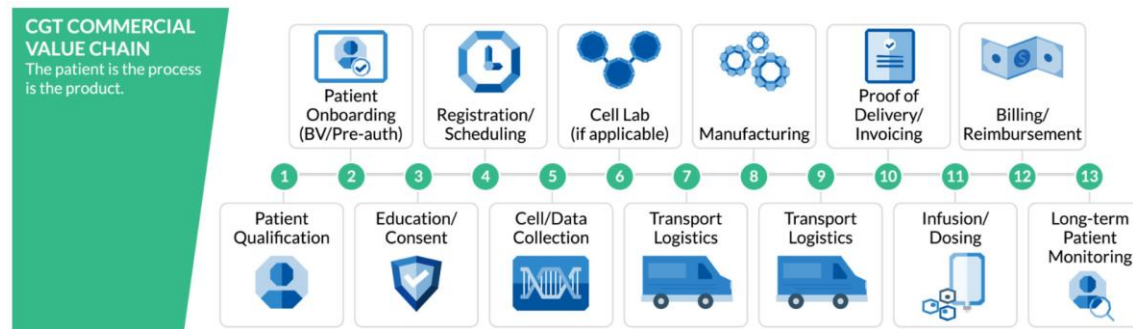
Future

- Enormous increase of number of transactions in C/G field since 2013
- Since 2020 reflecting back in a sales growth trend from 6,9 billion to 43,7 billion USD

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- Helicopter view C/G Landscape
 - ATMP's
 - Figures
- **Deep dive: Cell & Gene Supply Chain**
 - Differences & Challenges



Deep dive: Cell & Gene Supply Chain

Differences between Cell Therapy and Traditional Biopharma Supply Chain

- Starting Material from Patient

Cell Therapy Production



Traditional Biopharma

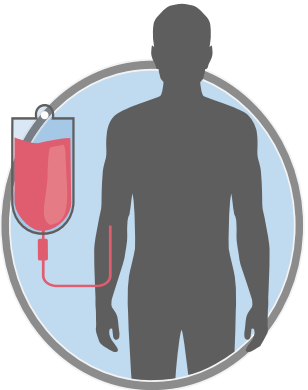


Deep dive: Cell & Gene Supply Chain

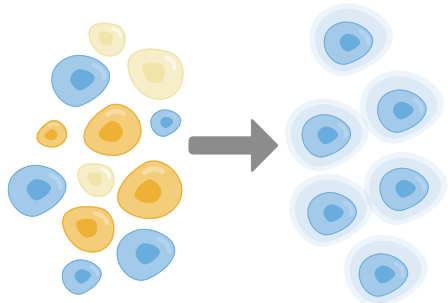
Starting Material from Patient

Apheresis

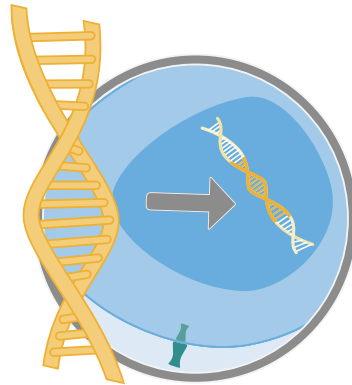
Collect patient's white blood cells



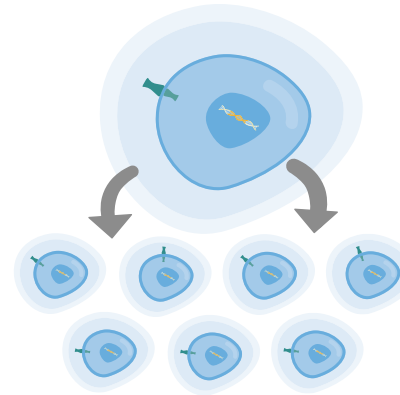
Isolate and activate T cells



Engineer T cells with CAR or TCR gene

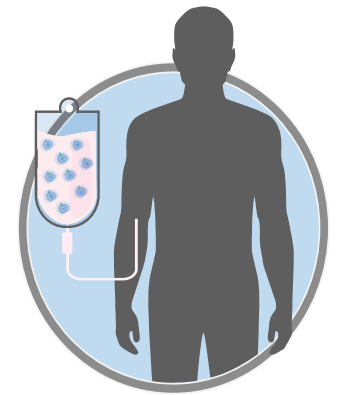


Grow and expand number of T cells



Infusion

Infuse patient with engineered T cells



Deep dive: Cell & Gene Supply Chain

Differences between Cell Therapy and Traditional Biopharma Supply Chain

- Starting Material from Patient
- Few/single suppliers of raw materials
- Timing & scheduling are critical
- Each patient is a unique batch
- Requires Chain of Identity (COI) and Chain Of Custody (COC)

Cell Therapy Production



Traditional Biopharma



Deep dive: Cell & Gene Supply Chain

Requires Chain of Identity (COI) and Chain of Custody (COC)



Deep dive: Cell & Gene Supply Chain

Differences between Cell Therapy and Traditional Biopharma Supply Chain

- Starting Material from Patient
- Few/single suppliers of raw materials
- Timing & scheduling are critical
- Each patient is a unique batch
- Requires Chain of Identity (COI) and Chain Of Custody (COC)
- No (yet) product Inventory

Cell Therapy Production

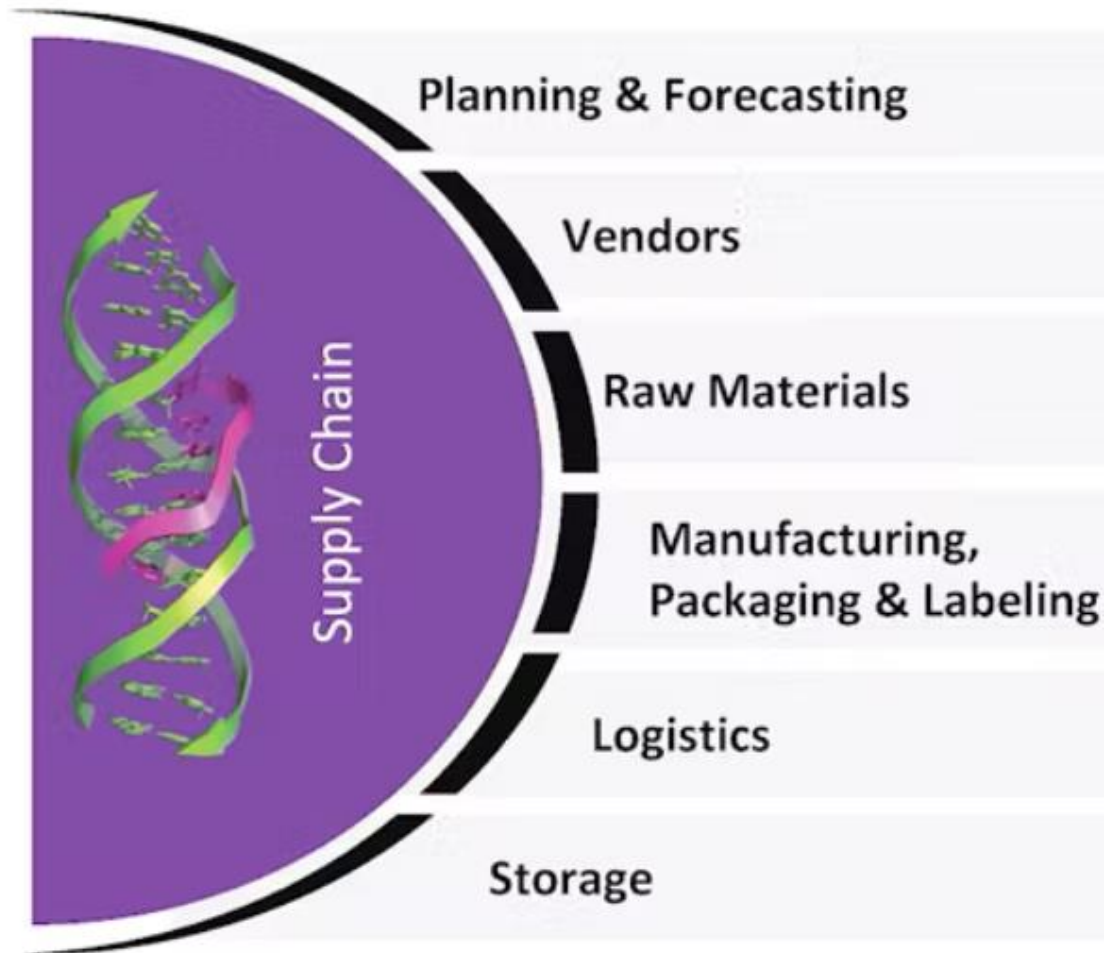


Traditional Biopharma



Deep dive: Cell & Gene Supply Chain

C/G Supply Chain Challenges



Demand, Capacity



Sourcing Requirements



Procurement, Tissue Collection



Expertise, Regulations, Traceability,
Internal, External



Controls, Reliability, Delivery,
Timelines, Conditions, Tracking

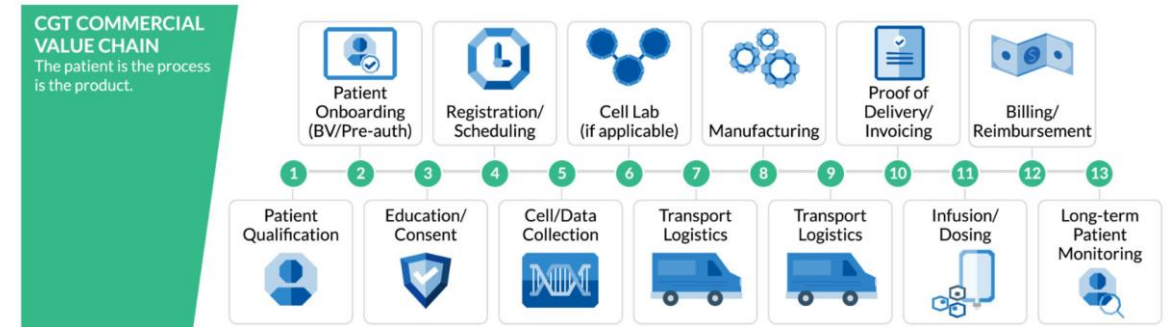


Capacity, Conditions (Temperature),
Time Period

Agenda

Topics

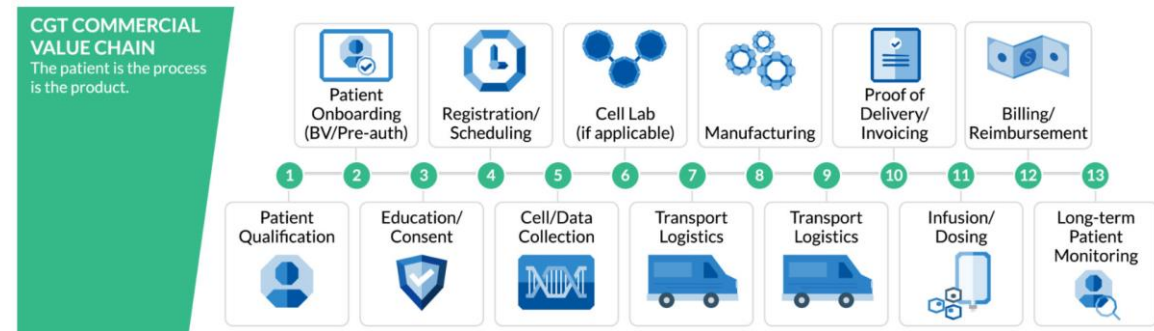
- Helicopter view C/G Landscape
 - ATMP's
 - Figures
- Deep dive: Cell & Gene Supply Chain
 - Differences & Challenges
- **Bringing it together: Appeal for orchestration to create a sustainable SC model**
 - **Increase of supply/demand versus the current challenges**



Closure

Bringing it together: Appeal for orchestration to create a sustainable SC model

- **Standardisation**
- **Automation**
- **People**
- **Financials**



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Datum 1 april 2022
Betreft Stand van zakenbrief geavanceerde therapieën

*Correspondentie uitsluitend
richten aan het retouradres
met vermelding van de
datum en het kenmerk van
deze brief.*



Thanks a lot for your attention!

SCIENCE SUPPLY LIFE

