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Whitepaper

LTIMindtree's T-Cell Therapy solution for the Cell-Gene Industry

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Abstract

This whitepaper is intended to share the insight on the challenges in the most sought after medical treatment, the cell-gene therapy process, specifically T-cell therapy.

This therapy is fast becoming the effective treatment model to treat cancer. Also, the paper highlights how the LTIMindtree's solution will assist the stakeholders, with the use of technology and digital transformation, overcome these challenges.

This whitepaper is pzrimarily for the following personas in Cell-gene or T-cell therapy program:

- **R&D Head in the CRO or Pharmaceutical industry**
- **Quality and Production Head**
- **Head of Digital Transformation**
- **Head of Supply-chain operation**
- **Solution Architect**
- **Life Science researcher**
- **Business Analyst**

The whitepaper covers 5 prime segments:

- Background and origin of the T-Cell therapy process
- Industry challenges faced in terms of delivering this treatment to the patients
- Key consideration in addressing the T-cell therapy challenges
- LTIMindtree's solution to address these challenges
- Solution deployment approach.

Background

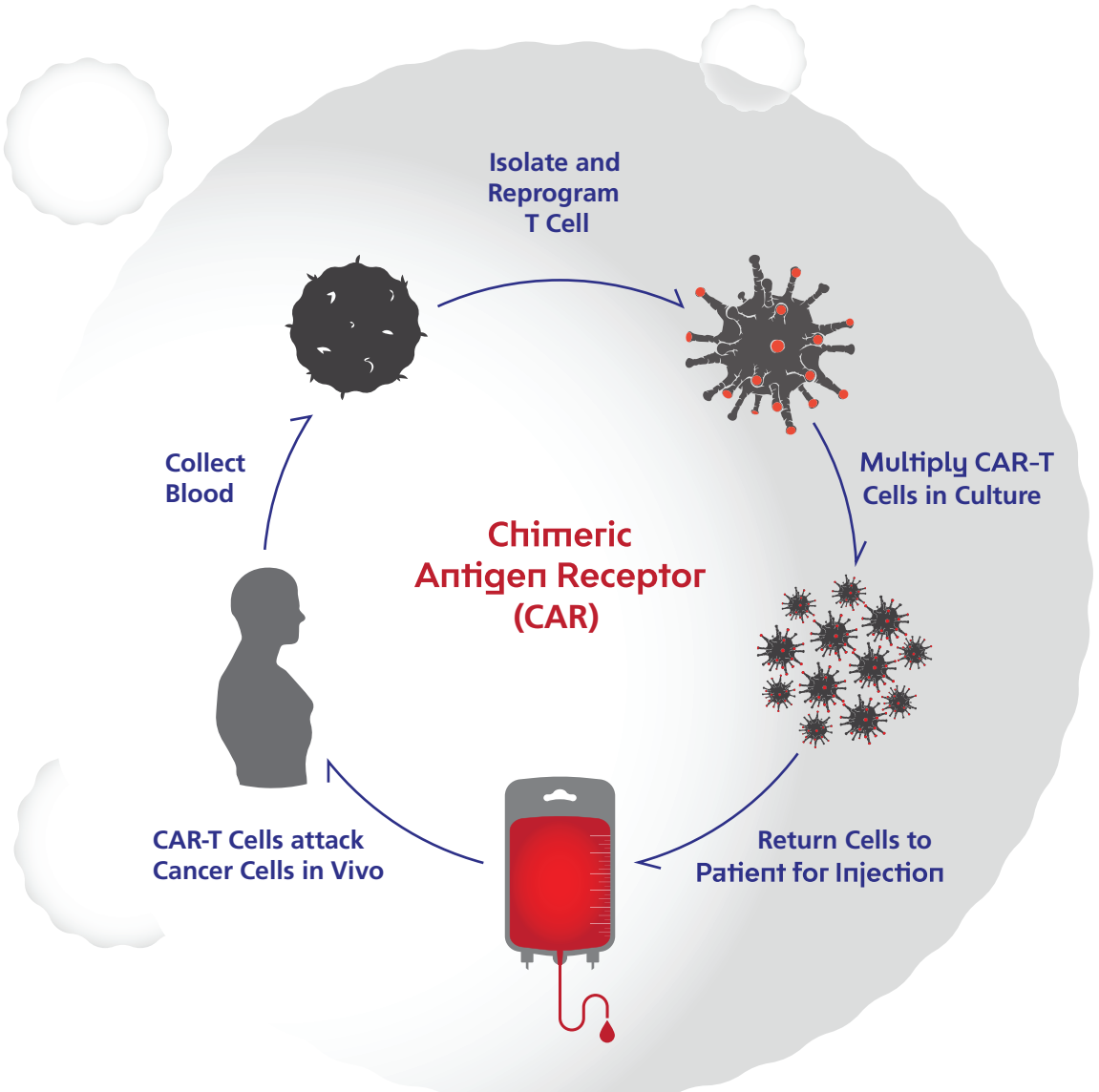
Cancer is one of the leading causes of death worldwide with over 10 million deaths in 2020, globally (as per WHO statistics), while this is true, it is also true that many forms of cancers can be cured if detected early and treated effectively.

Over the years, several conventional approaches for the diseases have been developed. However, due to their limitation effectiveness and heterogeneity of cancer cells, there is a constant search for therapeutic approaches with improved outcome, such as immunotherapy that utilizes and enhances the normal capacity of the patient's immune system.

Chimeric antigen receptor (CAR) T-cell cancer therapy—is being regarded as one of the fastest emerging curative therapies in the fields of biopharma cells. CAR-T cells are genetically engineered with T-lymphocytes cells that produce an artificial (chimeric) T-cell receptor targeted specifically to act and kill the tumour expressing that protein.

In this therapy, cells are removed from the donor (Patients or Donors) in the form of blood samples, genetically altered and returned or infused into the patient as per defined treatment protocols. Patient's blood sample tracking and tracing is a very critical requirement as well as maintaining the patient's privacy.

CAR-T cell therapy is unique in its need to closely track the patient identity from apheresis through manufacturing, infusion, and long-term follow up, making sure that the right patient receives the right treatment every time. In the entire therapy, biological samples are drawn from patients, transferred to GMP facilities for engineering, incubated and transferred back to patients for infusion, refer to stages of treatment shown in the figure below:



Industry Challenges

The entire sample supply chain is highly personalized, that requires management of samples to be handled safely, reliably in a temperature-controlled environment. Traceability of sample to patient credentials at every stage of processing and tracking sample flow as per treatment protocols, becomes mission critical for success of CAR-T therapy

CAR-T cell therapy is highly personalized protocol, in its nature, which adds to complexity in manufacturing and logistics process. End-to-end automation is key to addressing these challenges and to enable the operations of CAR-T cell therapy at scale. CAR-Ts & other CGTs are often managed in cryo state, i.e. handled under frozen condition (-150°C, -238°F) and need to be delivered within a very narrow specific time period, which usually requires specialized transportation– mainly, a dedicated cold chain courier service

Moreover, based on the Mckinsey study,

> **"The unmet need for CGTs in Europe is significant. The estimated patient population for just four indications addressed by CGTs today is 385,000, roughly three times as large as the equivalent US cohort".**

This means, there is a big gap between demand & supply.

One of the biggest challenges in the entire CAR-T process is associated patient-centric and personalized logistics.
Digital technologies have shown promise to address these logistical challenges through adoption of Cloud computing services, IoT Services as well as Track & Trace labelling solutions

Automation solutions addressing the requirements of CAR-T therapy need to address the requirements of a fully personalized sample supply chain, that links up the sample process flows, logistics and handling processes, conversion process, and infusion steps with patient credentials at every stage of treatment. The samples drawn, are subjected to handling and changes at multiple stages across the entire manufacturing chain, that needs to be addressed by Track & Trace solution completely. Technological advancement coupled with new methods needs to be looked into to bridge the gap .

Key considerations to address CAR-T Supply Chain solution requirements

Some of the important considerations for managing treatment sample logistics for CAR-T therapy include:

Personalized treatment model

CAR-T therapy is part of Cell & Gene Therapy treatment which is largely a Make-to-Order, Patient specific therapy.

Autologous nature of materials

Being Autologous, sample stocks are sourced from Patients/Donors themselves and is the first step in the production process. Quality and viability of cellular material is highly variable and is influenced by the Patients age, treatment history and multiple other factors. These factors have weightage on the sample volumes collected, which in turn determine the logistics tolerances. CAR-T treatment are not driven by Volume/Scale as it works on the principle of “One Patient – One Batch” – which in turn drive the supply chain requirements

Traceability , Chain of custody & Identity protection are mission critical apects across sample life cycle

The individualized nature of these treatments is crucial for their effectivity. This translates to the absolute requirement that each patient receives his/her own CGT product to avoid devastating toxicity, enabled by consistent end-to-end monitoring and tracking of their therapy.

Tracking the samples transit and recording the temperature condition, transit time and alerting the stakeholders, in cases of excursions or deviations, can make the life changing difference to treatment efficacy in case of CGTs.

Industry solution that assists to overcome supply chain issues Industry solution that assists

LTIMindtree's solution leverages technology effectively in T-Cell Therapy deployment solution. Since the therapy is meant for patient-centric at a point in time, optimum capacity planning at the production centre, auto-notifications to transporters and next in command of the chain are the few challenges that can be handled using latest technology.

LTIMindtree's labelling and T-Cell Therapy Supply Chain Solution is designed to address CAR-T / CGT sample flow tracking as well as to adhere to regulatory compliance requirements, such as HIPPA, GMP, etc.

The solution is built on SAP BTP (Business Transformation Platform- Cloud technology) and is available on all devices such as mobiles, pads, laptops, desktops, etc. This enables the end-users, such as patients, doctors and several other personas in the chain of events to get the visibility/ transparency of the process, identify any roadblocks and plan for next course of action thus giving a complete visibility of events in the cycle time to complete vein to vein process.

Auto-notifications to external parties, such as transporters, or internal members, who are next in the chain of events, enables the level of readiness required in such a crucial treatment procedure.

The patient’s samples are uniquely identified and the external batch-number which results in processing the correct blood sample with T-cells and returned to the same patient in accordance with the required timelines.

The solution is also designed in a way that can carry out better capacity planning while handling multiple regions, by centrally monitoring the activities. By addressing these objectives, the LTIMindtree's T-Cell Therapy deployment solution caters to a larger audience in Cell-Gene Therapy segment.

Deployment Approach

The LTIMindtree's T-Cell Therapy Deployment solution is an SAP-Certified solution. The package can be deployed within 3-4 weeks (without customization).

The LTIMindtree T-Cell Therapy deployment solution will help the CGT industry segment in a long way and with LTIMindtree's continuous improvement program in the Life-Science solutions, a collaboration will be mutually beneficial.

Following steps needs to be executed:

Write an email to LTIMindtreeLIFE_CART@ltimindtree.com to get connected with our team.

Speak with our SMEs.

Take a look at our video and brochure for an insight of the solution.

In case the solution fits to your requirements, lets sign an NDA for next steps.

Conclusions

Accurate production capacity planning, tracking of samples and automation-n-digitalization of sample supply chain is mission critical as well as key imperative for the success of CGT treatment. LTIMindtree's T-Cell Therapy Deployment solution is a unique, out of box, custom built solution that integrates with the existing SAP suite as well as Hospital Management systems and provides a quick robust sample tracking across its lifecycle from apheresis to infusion.

This solution is thoroughly tested for different business scenario , certified by SAP and has a promise of quick deployment to address this emergent need of the CGT-industry segment.

Reference

Mckinsey Study – June-2021

https://www.mckinsey.com/industries/life-sciences/our-insights/a-call-to-actionopportunities-and-challenges-for-cgts-in-europe

About the Author

Amod Gurjar

Amod has over 25 years of experience in the field of IT , Consulting and Services and has primarily worked in Life-science industry. He has extensive experience in project delivery in pharmaceutical manufacturing industry under GAMP guidelines. He has developed various solutions automation and digital transformation solutions pertaining to the industry which have been certified by SAP.

Gopal Rangaraj

Gopal is a business technology professional with over 30 years of experience in Technology leadership roles in Pharma, Life Sciences, Manufacturing industries and Business Consulting & Technology Services delivery for customers in India & across the globe. Gopal has worked as CIO & Head of IT in Pharma, Life Sciences organization for over 12 years, and has been responsible for driving for Automation & Digital technology solutions in a GMP environment. Gopal has worked extensively in areas of GxP automation, in the areas spanning across, Clinical studies, Pharma Manufacturing, Quality Control, Quality Assurance, and Logistics automation for Biotech, Pharma, Blood Plasma Proteins and Recombinant manufacturing businesses.

Shrikant Shelke

Shrikant has over 22 years of experience in Supply Chain Management with focus on Procurement which includes 16+ years of consulting experience in P2P area and 6 years of domain experience in electrical and electronics industry

He has a rich experience in leading Business Process transformation projects for large global customers delivering Best-in-class solutions, end to end Implementations, Enhancement and Production Support Projects

His expertise in Implementation of Source To Pay solutions with multiple technologies such as S/4HANA, Ariba, Coupa as well as expertise in Support Operations transition for global firms with complex system landscape.

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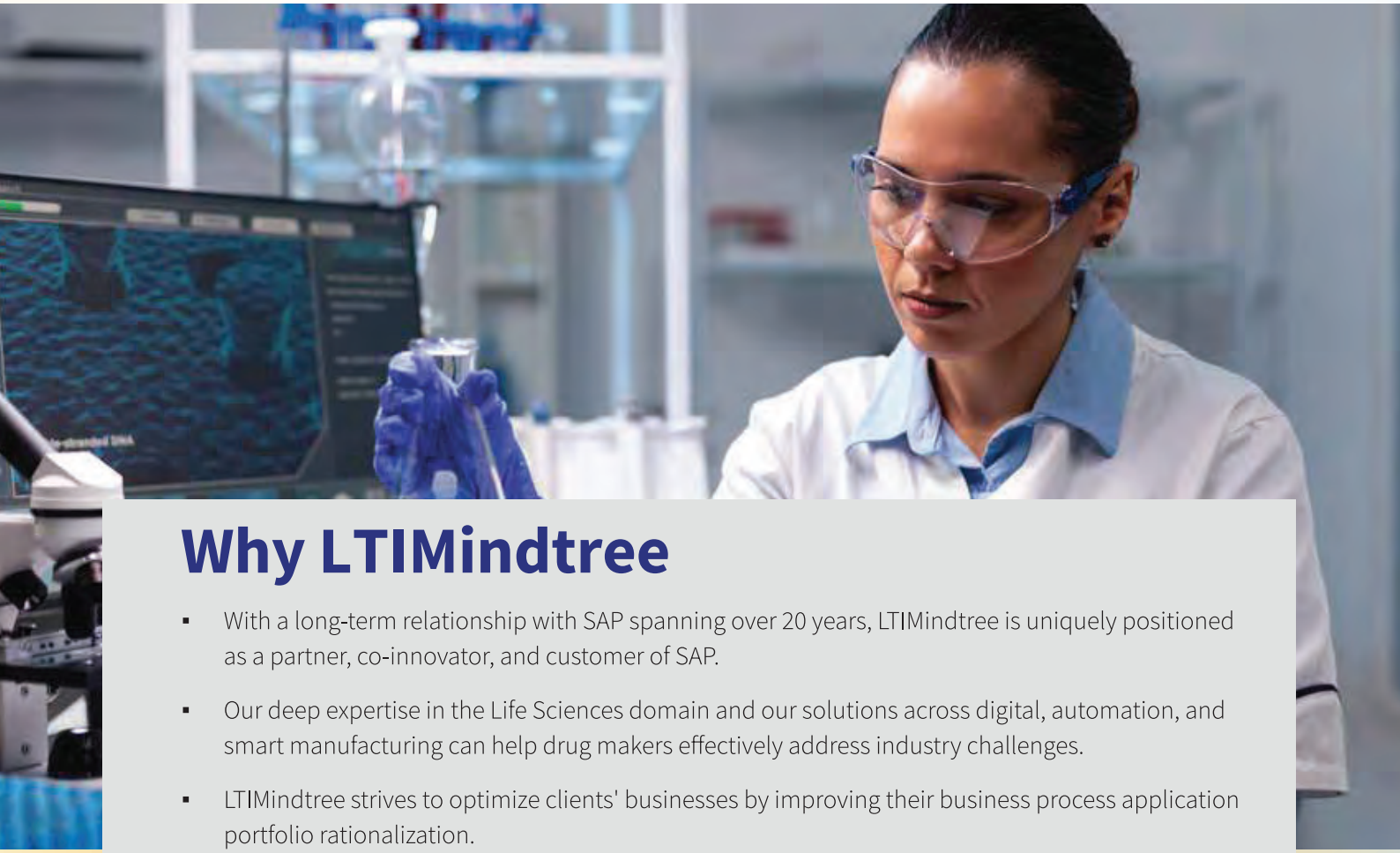

Why LTIMindtree

- With a long-term relationship with SAP spanning over 20 years, LTIMindtree is uniquely positioned as a partner, co-innovator, and customer of SAP.
- Our deep expertise in the Life Sciences domain and our solutions across digital, automation, and smart manufacturing can help drug makers effectively address industry challenges.
- LTIMindtree strives to optimize clients' businesses by improving their business process application portfolio rationalization.

Visit our website today to learn more about our expertise in the life sciences domain, our solutions across digital, automation, and smart manufacturing, and how we can help you optimize your business processes:

https://www.ltimindtree.com/enterprise-solutions/sap/life-science/

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About LTIMindtree

LTIMindtree is a global technology consulting and digital solutions company that enables enterprises across industries to reimagine business models, accelerate innovation, and maximize growth by harnessing digital technologies. As a digital transformation partner to more than 700 clients, LTIMindtree brings extensive domain and technology expertise to help drive superior competitive differentiation, customer experiences, and business outcomes in a converging world. Powered by 84,000+ talented and entrepreneurial professionals across more than 30 countries, LTIMindtree — a Larsen & Toubro Group company — combines the industry-acclaimed strengths of erstwhile Larsen and Toubro Infotech and Mindtree in solving the most complex business challenges and delivering transformation at scale. For more information, please visit http://www.ltimindtree.com.