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Tisagenlecleucel wins second FDA approval

This article covers the recent FDA approval of tisagenlecleucel use in adults with relapsed or refractory large B-cell lymphoma. A glimpse of the top assignees working on CAR-T technology and the patent filing trend for CAR-T based therapeutics are also presented.

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Edge Computing in Internet of Things

This article notifies the general availability of Microsoft's Azure IoT Edge. A quick glance at the top assignees within Edge computing for IoT and a few products available in the market are also listed.

Tisagenlecleucel Wins Second FDA Approval

On May this year, <u>FDA approved</u> tisagenlecleucel for adults with relapsed or refractory large B-cell lymphoma. The approval was based on a single-arm, open-label, multi-center <u>phase 2 trial</u>. The trials related to the drug were conducted across several countries including United States, Australia, Austria, Canada, France, Germany, Italy, Japan, Netherlands and Norway. Tisagenlecleucel – marketed as Kymriah[®] by Novartis - is the <u>first gene therapy</u> to be approved in the US. It was initially approved to treat only certain children and young adults with B-cell acute lymphoblastic leukemia. With the recent FDA approval for adults, this therapy is expected to be widely used.

Tisagenlecleucel is a targeted immunotherapeutic made from genetically modified T-cells having chimeric antigen receptors (CAR-T). The engineered T-cells express a CD19-targeting moiety on their surface that initiates a cascade resulting in target cell destruction. Novartis collaborated with <u>Dr. Carl June</u> from University of Pennsylvania to develop tisagenlecleucel.

Apart from Novartis, Kite Pharma (now <u>acquired by Gilead Biosciences</u>) also won an FDA approval in October 2017 for their product <u>Yescarta (axicabtagene ciloleucel)</u>. The safety and efficacy of Yescarta were established in a <u>multicenter clinical trial</u> of more than 100 adults with refractory or relapsed large B-cell lymphoma. The complete remission rate after treatment with Yescarta was 51 per cent. Most of the patent filings in the space are owned by academic and research institutes such as University of Pennsylvania, Memorial Sloan Kettering Cancer Institute and the US Dept. of Health and Human Services. The major commercial players in the CAR T-cell space are Cellectis and Novartis. There are several instances of collaborative patent filings between Universities and commercial entities.



FIG. 1 illustrates the count of patent families distributed among the Top assignees. 1750 patent families focus on CAR T-cells for various applications. Only filings from the top assignees have been shown in the chart. One member per patent family has been considered to plot this chart.

Dr. Carl June from the University of Pennsylvania is a prolific inventor in this space. He is listed in over 350 patent applications belonging to 60 patent families focussing on CAR-T (FIG. 2). Dr. Carl June was recently named in 2018 Time Magazine's 100 Most Influential People in the world for his research related to CAR-T and contribution to cancer treatment.



FIG. 2 depicts the publication trend of Dr. Carl June's patents and patent applications. The patent publication count for 2018 is incomplete due to lag in publication. All applications have been considered to plot this chart.

Although CAR-T is making waves in cancer therapy, several challenges remain ahead before CAR-T therapies become widely applied. The major <u>limitations</u> of designing the chimeric receptors are the <u>heterogeneity of cancer antigens</u>, the <u>inhibitory factors in suppressive tumor microenvironment</u>, indefinite <u>spatial distance between CART-cell and its target cell</u>, and the <u>off-tumor toxicities of</u> <u>CAR-T cell therapy</u>. Research efforts in addressing these limitations are on-going. With more trials and research related to this therapy we may have at our disposal an additional weapon in our anti-cancer arsenal.

Edge Computing in Internet of Things

<u>Microsoft's Azure IoT Edge</u> has gone live since the last week of June, and aims to help businesses better collect and act on Internet of Things (IoT) data in real time. Microsoft stated that Azure IoT Edge will be open sourced, will include broad language support for module SDKs, and improved security measures. The three features launched alongside the available services are: 1) Device provisioning service that allows customers to securely provision tens of thousands of devices to scale up edge deployments faster, 2) Security manager that offers device protection against security vulnerabilities to original device manufacturers based on their choice of Hardware Secure Modules (HSM), and 3) Automatic device management that allows for scaled deployment of IoT Edge modules to a set of devices based on the device metadata.

While cloud computing still remains a significant aspect of how businesses work, IoT initiatives such as Azure IoT Edge encourages investment in computing solutions closer to the "ground" to alleviate setbacks with cloud computing such as bandwidth, security and latency. This is the reason why "fog computing" (computing intelligence at local area network level) or "edge computing" (computing intelligence at local area network level) or "edge computing" (computing intelligence present directly in a device) is a model campaigned by few <u>leading IoT technology players</u> including Cisco, IBM, and Dell. When a <u>private Edge cloud network</u> is connected to IoT devices, it has several advantages such as <u>increased performance</u> of the system and <u>reduced latency</u>. Apart from these, another factor for choosing Edge may be for securing the <u>privacy of data</u> captured by IoT devices.

A quick look at the patent filings claiming Edge or Fog computing revealed Intel has the most number of filings in this space.



FIG. 3 Bar chart depicting the top assignees in this space based on a quick search. INTEL seems to be leading the Edge computing in IoT space based on number of patent families filed. Shenzhen Shenglu IoT Communication and Xidian University are based out of China.

Futurewei Technologies is one of Huawei's American operations.

Some of the products/services available in the market have been briefed below:

1. Intel's Xeon D-2100 Processor



FIG. 4 Intel's Xeon D-2100 Processor

Intel's Xeon D-2100 Processor offers the following services: data acquisition and device control, data security features between sensors, gateways, and the cloud, more secure, hands-free device on boarding, Edge-data collection, storage, and analysis, real-time business intelligence for optimized decision support, autonomous decision-making, and optimized interaction and decision-making across devices, and Edge-platform flexibility and scalability.

2. Cisco Kinetic

<u>Cisco Kinetic</u> aims to resolve common challenges in IoT environments where devices and applications are highly distributed. It provides a <u>gateway management module</u>, an <u>Edge and Fog processing</u> <u>module</u>, and a <u>Data Control Module</u>.

3. Smartiply IoT Gateway SH-1601



FIG. 5 Smartiply IoT Gateway SH-1601

Smartiply IoT Gateway SH-1601 is a next generation device designed to deliver innovative connectivity solutions to enhance customer experience and enable Edge intelligence to improve operational efficiency

4. Huawei's EC-IoT

<u>Huawei's EC-IoT</u> offers the following benefits to industries: open Edge computing, cloud based centralized management, and visualized operation and maintenance (O&M)

With patent filings increasing in the last few years, the market opportunities for **Edge computing** and **Fog computing** based solutions are expected to increase. It is forecasted that there will be aspects of Fog that become features of existing devices and software, working in tandem with stand-alone, single-purpose Fog nodes.





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