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Top Healthcare Innovations in 2021

March 2022

Executive Summary

	Innovations	Focus Area	Uniqueness
1	ADUHELM® (aducanumab-avwa)	Treatment of Alzheimer disease	First drug to slow cognitive decline in people living with Alzheimer's and the first new medicine for the disease in nearly two decades
2	Wegovy (semaglutide)	Weight loss	First approved drug for chronic weight management in adults with obesity/overweight since 2014
3	RTS,S/AS01 (MosquirixTM)	Prevention of malaria disease	First and, to date only, vaccine shown to have the capability of significantly reducing malaria
4	Tracheal Transplant	Treatment of tracheal damage	World's first human tracheal transplant
5	Jemperli (Dostarlimab)	Treatment of endometrial cancer	First immunotherapy
6	Semglee (Insulin glargine-yfgn)	Improvement in glycemic control in patients with diabetes	First interchangeable biosimilar insulin product
7	VUITY™ (Pilocarpine HCl ophthalmic solution) 1.25%	Treatment of age-related blurry near vision	First and only FDA-approved eye drop
8	Leqvio® ® (Inclisiran)	Prevention of malaria disease	First and only small interfering RNA therapy
9	Bridge-Enhanced ACL Restoration (BEAR)	Treatment of ACL tears	First medical technology to clinically demonstrate that it enables healing of a patient's torn ACL
10	Cytalux pafolacianin	Detection of ovarian cancer	First targeted fluorescent imaging agent

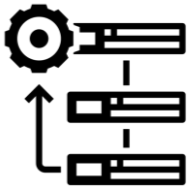
Context and Approach

Approach

1 Capturing & Filtering Innovations

- Tracked and captured ~150+ recent healthcare innovations of 2021 that would be a game changer in healthcare
- Gathered key information for each innovations such as number of lives affected, focus area, commercialization and complexity of problem solved to understand the impact of each innovation

2 Prioritizing & Rating



- Each innovation was given a weightage (60:40) & a rating on a scale of 1 to 5 based on two criteria: its impact on future of health and commercialization
- Innovations were prioritized based on possible scores & different pre-assigned weights for each innovation

3 Analysing Future Trends

- Top 10 innovations were identified based on the scores of their uniqueness and impact of the different captured parameters
- Finally, the top 10 innovations were analysed deeply to understand how it will be beneficial for future health and how it can be served as powerful catalyst

Top 10 Healthcare Innovations

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1 ADUHELM® (aducanumab-avwa)

The first drug to slow cognitive decline in people living with Alzheimer's and the first new medicine for the disease in nearly two decades

- Aduhelm is developed by biotechnology company "Biogen" in partnership with Japanese drugmaker "Eisai" that attempts to treat a possible cause of the neurodegenerative disease, rather than just the symptoms
- Aduhelm is an amyloid beta-directed antibody indicated to treat Alzheimer's disease
- Aduhelm is the only therapy that targets defining pathologies of Alzheimer's by reducing amyloid beta plaques in the brain which will to improvement in cognition and functioning in patients with AD

This breakthrough drug provides a meaningful therapeutic advantage over existing treatments by being the first therapy to target and affect the underlying disease process of a widespread life-threatening illness

Rationale

Prevalence

AD is the most frequent cause of Dementia (**60%-70%** of all cases)
More than **55 million** people live with dementia worldwide

Impact

In clinical trials, Aduhelm reduced amyloid beta plaques by **59% to 71%** at **18 months** of treatment

Acceptance

Aduhelm was approved using the accelerated approval pathway, which can be used for a drug for a serious or life-threatening illness

Sources: Biogen, FDA

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2 Wegovy (Semaglutide)

The first approved drug for chronic weight management in adults with general obesity or overweight since 2014

- Semaglutide 2.4 mg is a GLP-1 receptor agonist, with 94% similarity to naturally occurring human GLP-1 hormone
- Semaglutide is indicated for adults who are obese (body mass index ≥30) or overweight (body mass index ≥27) with at least one weight-related medical conditions, such as type 2 diabetes, hypertension, and high cholesterol
- Semaglutide is the once-weekly injection designed to balance out hunger hormones when used in combination with diet and exercise

The drug has the potential to transform obesity management and help millions of people living with obesity

Rationale

Prevalence

In 2020, more than **2 billion** adults, 18 years and older, were overweight. Of these, over **650 million** were obese

Impact

Over 68 weeks, participants who received the drug lost, on average, nearly **15%** of their weight — a stark difference from members in the placebo group, who lost **2.4%**

Acceptance

FDA's approval offers adults with obesity or overweight a beneficial new treatment option to incorporate into a weight management program

Sources: Business Insider, Novo Nordisk, A mansiq Biotech

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3 RTS,S/AS01 (Mosquirix™)

The first and, to date only, vaccine shown to have the capability of significantly reducing malaria, and life-threatening severe malaria

- The RTS,S vaccine was developed by a public–private partnership in 2001 between GSK and PATH's Malaria Vaccine Initiative
- This first-generation malaria vaccine demonstrates modest efficacy against malaria illness and holds promise as a public health tool, especially for children in high-transmission areas where mortality is high
- The vaccine is designed to prevent the parasite from infecting the liver, where it can mature, multiply, reenter the bloodstream, and infect red blood cells, which can lead to disease symptoms

Catering to a prevalent disease, this innovation has already proven its merit for healthcare industry as the results are promising and recognized by WHO itself

Rationale

Prevalence

In 2020, there were an estimated **241 million** cases of malaria worldwide
The estimated number of malaria deaths stood at **627,000** in 2020

Impact

Significant reduction **(30%)** in deadly severe malaria according to WHO's pilot program
By one estimate, it will save tens of thousands of children each year

Acceptance

Since October 2021, WHO recommends broad use of the malaria vaccine among children living in regions with moderate to high P. falciparum malaria transmission

Sources: WHO, NCBI

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4 Tracheal Transplant

World's first-ever human tracheal transplant performed

- Surgeons at New York City-based Mount Sinai performed the first human tracheal transplant during an 18-hour procedure
- Mount Sinai's historic procedure resulted from 30 years of research, much of it focused on how to revascularize, or provide blood flow to the trachea which had been one of the largest barriers to successfully transplant the organ
- It has the potential to save the lives of thousands of patients worldwide who have tracheal birth defects, untreatable airway diseases, burns, tumors, or severe tracheal damage from intubation, including those who had been hospitalized with COVID-19 & placed on a ventilator

With its recent first successful implication, the treatment is believed to revolutionize the current process and provide a sustainable long term solution

Rationale

Prevalence

Thousands of adults and children have died each year as a result of tracheal damage

Impact

The trachea transplant recipient got an opportunity to breathe through mouth for the **first time in six years** after **successful revascularization**

Acceptance

In April 2021, Mount Sinai Surgeons performed the first complete surgical transplant of a windpipe

Source: Mount Siani

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5 JEMPERLI (Dostarlimab-gxly)

First immunotherapy used for the treatment of recurrent or advanced endometrial cancer with deficient mismatch repair (dMMR)

- Dostarlimab is indicated for the treatment of adult patients with mismatch repair-deficient (dMMR) recurrent or advanced endometrial cancer
- JEMPERLI was discovered by AnaptysBio and licensed to TESARO, Inc., under a Collaboration and Exclusive License Agreement signed in March 2014
- JEMPERLI is a programmed death receptor-1 (PD-1)-blocking antibody that binds to the PD-1 receptor and blocks its interaction with the PD-1 ligands PD-L1 and PD-L2

Being given the breakthrough therapy designation by the FDA, this drug has the potential to reduce the risk of a deadly disease in patients

Rationale

Prevalence

Prevalence of dMMR across solid tumours in the US has been estimated at **14%**
60,000 women are diagnosed with endometrial cancer in the US each

Impact

Study results showed an overall response rate of **42%; 93%** of responders had a duration of response of ≥6 months

Acceptance

In April 2021, the FDA granted accelerated approval for dostarlimab
In August 2021, FDA approved a new indication for JEMPERLI (dostarlimab-gxly)

Sources: GSK, Clinical Trials Arena

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6 SEMGLEE® (Insulin glargine-yfgn)

The first interchangeable biosimilar insulin product, indicated to improve glycemic control in adults and pediatric patients

- SEMGLEE is a prescription long-acting man-made-insulin used to control high blood sugar in adults and children with type 1 diabetes and in adults with type 2 diabetes
- Semglee (insulin glargine-yfgn) is both biosimilar to, and interchangeable with (can be substituted for), its reference product Lantus (insulin glargine), a long-acting insulin analog
- FDA approval gives Semglee 12 months of product exclusivity before the next interchangeable biosimilar to Lantus can be approved

The innovative drug is believed to drastically lower the costs of treatment for a very common disease and catalyzing the growth of such mechanisms in other areas

Rationale

Prevalence

About **422 Mn** people worldwide have diabetes &**1.5 Mn** deaths are directly attributed to diabetes each year

Impact

Biosimilar insulin product can provide patients with **additional safe, high-quality and potentially cost-effective** options for treating diabetes

Acceptance

FDA approved in mid 2020 & the interchangeable status in July 2021 Viatris & Biocon launched branded & unbranded versions of the biosimilar in 2021

Sources: Viatris, FDS, WHO, AJMC

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7 VUITY™ (Pilocarpine HCl ophthalmic solution) 1.25%

The First and only currently available eye drop to treat age-related blurry near vision (presbyopia)

- VUITY is a once-daily prescription eye drop that improves near and intermediate vision for adults with age-related blurry near vision or presbyopia
- VUITY is an optimized formulation of pilocarpine, an established eye care therapeutic, delivered with pHast™ technology, which allows VUITY to rapidly adjust to the physiologic pH of the tear film
- VUITY uses the eye's own ability to reduce pupil size, improving near and intermediate vision while maintaining distance vision

Novel, safe, well-tolerated and effective alternative to current options for managing vision problems

Rationale

Prevalence

Presbyopia is a common & progressive eye condition that affects **128 million** Americans, or nearly half of the U.S. adult population

Impact

Participants treated with VUITY shown **significant improvement** in near vision in low light conditions without a loss of distance vision versus the placebo on day 30 at hour 3

Acceptance

FDA approved & it's now available by prescription in pharmacies nationwide

Source: AbbVie

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8 Leqvio® (Inclisiran)

The first and only small interfering RNA (siRNA) therapy to lower low-density lipoprotein cholesterol (also known as bad cholesterol or LDL-C)

- Leqvio is a revolutionary approach to lower LDL-C with two doses a year, after an initial dose and one at three months
- Leqvio is indicated in the US as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) who require additional lowering of LDL-C
- Leqvio reduces the amount of LDL-C in the bloodstream by improving the liver's natural ability to prevent the production of a protein that plays a role in keeping circulating cholesterol levels high

Though this drug is not the only solution to the disease it caters to, it's approach to lower the impact is first of its kind and hence deserves a place in top innovations of 2021

Rationale

Prevalence

ASCVD affects **30 million** Americans **74%** of ASCVD patients have low-density lipoprotein cholesterol (LDL-C) levels ≥70 mg/dL, including **67%** at very

Impact

Leqvio provides effective and sustained LDL-C reduction of up to **52%** vs. placebo for certain people with atherosclerotic cardiovascular disease

Acceptance

FDA approved Novartis Leqvio® (inclisiran), first-in-class siRNA to lower cholesterol & keep it low with two doses a year

Source: Novartis

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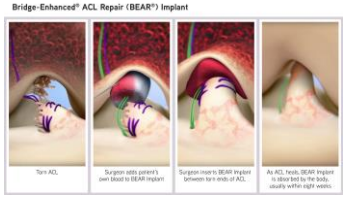
9 Bridge-Enhanced ACL Restoration (BEAR) implant

The first medical technology to clinically demonstrate that it enables healing of a patient's torn ACL (Anterior Cruciate Ligament)



- The BEAR implant is an alternative to ACL reconstruction, which typically requires harvesting tendons and sometimes bone from another part of the patient's body or a deceased donor
- The BEAR implant has been designed to serve as a bridge between the two ends of the torn ACL. The surgeon injects a small quantity of the patient's own blood into the implant & inserts it between the torn ends of the ACL via minimally invasive procedure
- The implant is indicated for skeletally broken-down patients as a minimum 14 years of age with a total fracture of the ACL that is amenable to suture repair

Implant is first new treatment for ACL tears in 30+ years; Enables injured ACL to heal itself

Rationale

Prevalence

Every year, approximately **400,000** ACL injuries occur in the U.S.

Impact

Compared to traditional ACL reconstruction, the implant is a **less invasive procedure** that restores the knee's natural anatomy and function

Acceptance

Granted FDA de novo approval for treatment of ACL tears in 2020 & now it's commercially available in U.S.

Sources: Businesswire, Miach Orthopeadics

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10 Cytalux (Pafolacianin)

Cytalux is the first targeted fluorescent imaging agent that illuminates ovarian cancer intraoperatively, enabling the detection of more cancer for removal

cytalux™ (pafolacianine) injection

- Cytalux is indicated for use in adult patients with ovarian cancer to help identify cancerous lesions during surgery. The drug is a diagnostic agent that is administered in the form of an intravenous injection before surgery
- Cytalux is used with a near-infrared fluorescence imaging system approved by the FDA for specific use with pafolacianin
- The drug Cytalux (pafolacianin) is said to improve a surgeon's ability to detect ovarian cancer during surgery on a patient

Backed by its clinical trial results, the drug is supposed to significantly improve the detection of a deadly disease thus providing the surgeons an upper hand in treatment

Rationale

Prevalence

More than **21K** new cases of ovarian cancer & more than **13k** deaths due to this disease by 2021, making it the deadliest of all cancers in the female reproductive system

Impact

It was reported that the drug helped identify **27%** of patients that had at least 1 lesion that was not seen on standard visual or tactile examination

Acceptance

After giving a priority review in March 2021, the FDA approved imaging drug pafolacianin for detection of ovarian cancer during

Sources: Title press, Newsbreezer, Cancernetwork

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Other Healthcare Innovations of 2021

Other important innovations of 2021 (1/2)

Innovations	Commercialization	Focus Area
Actemra (Tocilizumab)	FDA approved	First biologic therapy to treat systemic sclerosis-associated ILD
Evkeeza™ (Evinacumab-dgnb)	FDA approved	First treatment that binds to and blocks the function of angiopoietin-like 3 for patients with homozygous familial hypercholesterolemia (HoFH)
Lutetium (Lu)-177 PSMA-617 (LuPSMA)	FDA granted priority review of NDA	An investigational PSMA-targeted radioligand therapy for the treatment of patients with metastatic castration-resistant prostate cancer
Biomilq	Made in lab by scientists; Available/Launch in about 3 years	World's first lab-grown breast milk
Abecma (Idecabtagene vicleucel)	FDA approved	First cell-based gene therapy approved for the treatment of multiple myeloma
Cabenuva drug	FDA approved	First injectable, complete regimen for HIV-infected adults that is administered once a month
The Galleri Test	Not yet approved; But it is available nationwide via prescription—for a price	Blood test to detects more than 50 types of cancers in people ages 50 year or older

Other important innovations of 2021 (2/2)

Innovations	Commercialization	Focus Area
Paige prostate software	FDA granted marketing authorization	First artificial intelligence (AI)-based software designed to assist pathologists in detecting prostate cancer
Swoop™	FDA cleared; License issued by Health Canada & commercially launched in Canada	World's first bedside MRI system formaging of the brain and head in patients of all ages
Empaveli (Pegcetacoplan)	FDA approved	First PNH treatment that binds to compliment protein C3
Laser-assisted inferior vena cava filter removal device	FDA granted breakthrough device designation	Intended for ablating tissue to remove an IVC filter when previous attempts at removal failed; IVC filters are used to treat patients with venous thromboembolism
BiovitalsHF®	FDA granted breakthrough device designation	First-in-class DTx for heart failure that augments traditional guideline-directed medical therapy
Graphene nanotubes	Developed	Allows prosthetic hands to use touchscreens
3D printing micro-resorbable implants	Announced Capability to develop	World first 3D-printing technique that can produce bioresorbable & micro-scale medical implants

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