Lambda Research Newsletter

April 2023

LAMBDA

Research Accelerated

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Clinical Research NEWSletter

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GLOBAL NEWS

1. Lambda and Medidata team up to automate clinical trial data

Lambda Therapeutics, a leading global Clinical Research Organization (CRO) headquartered in Ahmedabad, India, has facilities and operations in North America (the USA and Canada) and Europe (London, and Warsaw, Poland). It offers a full spectrum of clinical trial solutions including Phase 2 to 4 late phase clinical efficacy and safety patient-based trials, early phase development, NCE trials, large molecule biosimilar assay development labs, data management, drug safety and pharmacovigilance and medical imaging, with more than 20 years of experience. The implementation allows both companies to offer their global clients a single unified platform that optimizes workflows, mitigates risk, cuts development costs, and secures data integrity.

Lambda Therapeutics will employ Medidata's Rave EDC, Rave RTSM, and Rave Imaging cloud-driven clinical solutions to access centralised data to address the entire clinical research process.

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2. Sanofi releases AVAXIM Junior in the UK

Therapy provides immunization against infection caused by hepatitis A in children aged 12 months to 15 years.

Sanofi has revealed that it is launching AVAXIM Junior across the UK. The treatment is an inactive hepatitis A vaccine for use in children aged 12 months to 15 years and has been developed to prevent infection caused by the hepatitis A virus.

The schedule consists of two vaccine doses injected by the intramuscular route, administered six to 36 months apart, although seven years can elapse between doses.

The launch follows pivotal data from 20 clinical studies across 14 countries in Europe, the Middle East, Asia and the Americas. These trials also involved over 6,200 children aged 12 months to 15 years who have received at least one dose of the vaccine.

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GLOBAL NEWS

3. Millions of cancer patients benefited from Elekta's Flexitron

Elekta has announced that around two million brachytherapy treatments have been delivered by healthcare providers using the company's Flexitron therapy.

Brachytherapy is a very precise type of radiotherapy that can be used to treat a wide variety of cancers. Also known as interventional radiotherapy, it sends a high level of radiation directly onto the tumour, while also minimising exposure to healthy tissue.

The treatment has been administered at a high dose rate (HDR) at several locations. One of the most notable sites – Amsterdam University Medical Centers (Amsterdam UMC) – recently contributed to the significant milestone by acquiring the 1,000th Flexitron treatment to be manufactured at Elekta's production facility in Veenendaal.

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4. Moderna cancer vaccine takes positive step

Moderna has announced that mRNA-4157 / V940 – its investigational cancer vaccine – in combination with Keytruda, Merck's anti-PD-1 therapy, has been granted Priority Medicines (PRIME) scheme designation by the European Medicines Agency (EMA).

It concerns the adjuvant treatment of patients with high-risk stage III / IV melanoma following complete resection. The vaccine mRNA-4157 / V940 stimulates an immune response by generating specific T cell responses based on the unique mutational signature of a patient's tumour.

The EMA awarded the PRIME scheme designation following positive data emerging from the phase 2b KEYNOTE-942 / mRNA-4157-P201 clinical trial. The results from this research will be shared at the American Association for Cancer Research (AACR) in mid-April.

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PHARMA INDIA

1. Sun Pharma launches novel therapy for dry eye disease in India

Sun Pharma launched a novel ophthalmology treatment, CEQUA®, in India for patients who have Dry Eye Disease (DED) with inflammation, a commonly occurring condition. CEQUA is the first dry eye treatment available in India that is delivered with nanomicellar (NCELL) technology.

Dry Eye Disease (keratoconjunctivitis sicca) or DED is a disease affecting millions of patients around the world. DED, as defined by the National Eye Institute (a division of the U.S. National Institutes of Health), occurs when the quantity and/or quality of tears fails to keep the surface of the eye properly lubricated.

The prevalence of DED in India is higher than the global prevalence and a large regional study pegged India's prevalence at 32%, of which 90% were affected with moderate/severe DED

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2. Biocon Biologics' new mAbs facility receives EU GMP certification for bBevacizumab

Biocon Biologics' integrated, multi-product, monoclonal antibodies (mAbs) drug substance manufacturing facility (B3) at Biocon Park, Bengaluru, has received a certificate of GMP compliance for an additional product, biosimilar Bevacizumab, from the representative European inspection authority, Health Products Regulatory Authority (HPRA), Ireland.

"The approval reflects Biocon Biologics' compliance with the highest international regulatory standards. It enables the company to continue addressing the needs of patients in the EU through its high-quality products.

"This (B3) facility, which is one of India's largest monoclonal antibodies (mAbs) manufacturing facilities, had received the EU GMP Certification for manufacturing biosimilar Trastuzumab last year. It was also awarded the 'Facility of the Year Award' (FOYA) with an 'Honourable Mention', by the International Society for Pharmaceutical Engineering (ISPE) in 2021" stated the company spokesperson.

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PHARMA INDIA

3. Pristyn-Indeed study shows Indian healthcare's high demand for nurses, lab technicians & physicians

Pristyn Care a healthcare service provider and Indeed, a job site in a joint study revealed that there has been a rise in demand for healthcare professionals in India with a 22.4% increase in job postings since January 2021 to January 2023. This demand has been further strengthened as healthcare chains and hospitals continue to expand across tier 1 and tier 2 cities, bolstered by the government's push on healthcare and nursing.

Jobseekers too are increasingly looking for opportunities in the healthcare segment, with a massive 52% increase in clicks for healthcare roles. The top roles among the healthcare related jobs posted on the platform are nurses (13%), lab technicians (10%) and physicians (8%).

While Bengaluru leads in the number of jobs for healthcare with over 8% of the total jobs share, Delhi (7%), Mumbai (6%) Chennai (6%), and Hyderabad (5%) are among the top five Indian cities for healthcare jobs posted in the portal. In addition, we are also seeing an increased demand in terms of job postings from tier 2 cities for healthcare jobs. Leading amongst these are Coimbatore, Ernakulam, Ahmedabad, Thiruvananthapuram and Kochi.

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REGULATORY ROUND-UP

1. FDA Commissioner & Chief Scientist Announce Decision to Withdraw Approval of Makena

Today, the U.S. Food and Drug Administration announced the final decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective today, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

The FDA approved Makena under the accelerated approval pathway in 2011 based on a determination that the sponsor had demonstrated a drug effect on an intermediate clinical endpoint that was likely to predict clinical benefit. The agency's approval included a requirement that the sponsor conduct a post marketing confirmatory study. The ensuing confirmatory study did not verify clinical benefit and the FDA's Center for Drug Evaluation and Research (CDER) proposed withdrawing the drug's approval in 2020. The sponsor requested a hearing, which was held in October 2022.

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2. FDA Moves Forward with Mail-back Envelopes for Opioid Analgesics Dispensed in Outpatient Settings

The U.S. Food and Drug Administration announced it is requiring manufacturers of opioid analgesics dispensed in outpatient settings to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers as an additional opioid analgesic disposal option for patients.

"Expanding impactful opioid disposal options, such as mail-back envelopes and in-home disposal, for patients to safely and securely dispose of their unused opioid medications is part of the agency's comprehensive approach to addressing the overdose crisis," said FDA Commissioner Robert M. Califf, M.D. "We believe these efforts will not only increase convenient disposal options for many Americans, but also reduce unfortunate opportunities for nonmedical use, accidental exposure, overdose and potential new cases of opioid use disorder. We're pleased to take this first critical step to increase mail-back envelope options in partnership with the U.S. Postal Service."

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REGULATORY ROUND-UP

3. FDA Approves First Orally Administered Fecal Microbiota Product for the Prevention of Recurrence of Clostridioides difficile Infection

The U.S. Food and Drug Administration approved Vowst, the first fecal microbiota product that is taken orally. Vowst is approved for the prevention of recurrence of Clostridioides difficile (C. difficile) infection (CDI) in individuals 18 years of age and older, following antibacterial treatment for recurrent CDI.

"Today's approval provides patients and healthcare providers a new way to help prevent recurrent C. difficile infection," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "The availability of a fecal microbiota product that can be taken orally is a significant step forward in advancing patient care and accessibility for individuals who have experienced this disease that can be potentially life-threatening."

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4. FDA issues continuous manufacturing advice to build an agile pharma industry

The FDA issued the International Council for Harmonisation (ICH) final guidance on the use of continuous manufacturing in drug production. This publication marks the FDA's proactive steps to ease the pharmaceutical's industry transition to these advanced processes, states the announcement.

While not binding, the document covers the regulatory and scientific considerations needed for the development and implementation of continuous manufacturing in pharma, and the guidelines are meant for both new and pre-existing products.

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MERGERS / ACQUISITIONS / COLLABORATIONS

1. GSK to acquire Canada-based late-stage biopharma company, BELLUS Health for US$ 2.0 billion

GSK plc and BELLUS Health Inc. announced that they have entered into an agreement under which GSK will acquire BELLUS, a Canada-based, late-stage biopharmaceutical company working to better the lives of patients suffering from refractory chronic cough (RCC) for US$ 14.75 per share of common stock in cash representing an approximate total equity value of US$ 2.0 billion (£1.6 billion).

The acquisition provides GSK access to camlipixant, a potential best-in-class and highly selective P2X3 antagonist currently in phase III development for the first-line treatment of adult patients with RCC.

It is estimated that 28 million patients suffer from chronic cough, with 10 million patients globally and 6 million in the United States (US) and European Union (EU) suffering from RCC for over a year. RCC is defined as a persistent cough for more than eight weeks that does not respond to treatment for an underlying condition or is otherwise unexplained. RCC significantly impacts quality of life, with patients suffering from depression (53%), urinary incontinence (~50%), pain, rib fractures, social withdrawal, and loss of sleep. There are no approved medicines for RCC in the US and EU.

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2. Mainz Biomed in collaboration with Instituto de Microecologia

Molecular genetics company Mainz Biomed, which focuses on the early detection of cancer, has announced that Spain's Instituto de Microecologia has been added to its expanding network of lab partners across Europe.

The company's main product, ColoAlert, is an efficacious home detection test for colorectal cancer (CRC) and by commercialising it throughout Spain and Portugal Mainz Biomed hopes the test's impact in Europe will continue to expand.

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MERGERS / ACQUISITIONS / COLLABORATIONS

3. Astellas Pharma agrees to buy Iveric bio for about $5.9bn

Astellas Pharma has entered into a definitive agreement to buy US-based biopharmaceutical company Iveric bio, in a deal valued at nearly $5.9bn.

Under the deal terms, the company, through Astellas US Holding's wholly owned subsidiary Berry Merger Sub, will acquire all the outstanding Iveric Bio shares for $40.00 in cash for each share.

Both the companies' Boards of Directors have unanimously approved the deal.

Iveric Bio is focused on the discovery as well as development of new therapies for retinal diseases with significant unmet medical needs.

astellas
Astellas Pharma Inc.

IVERIC BIO

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DRUGS: APPROVALS AND LAUNCHES

1. GSK launches shingles vaccine, Shingrix in India

GlaxoSmithKline Pharmaceuticals (GSK) has launched Shingrix (zoster vaccine recombinant, adjuvanted) in India, for the prevention of shingles (herpes zoster) and post-herpetic neuralgia in adults aged 50 years and above. Shingrix is a non-live, recombinant subunit vaccine to be given intramuscularly in two doses. Shingles are caused by the reactivation of the varicella-zoster virus (VZV), the same virus that causes chickenpox.

A seroprevalence study in Indian subjects showed that by the age of 40 years more than 90 per cent had this virus in their body and were vulnerable to shingles. Shingles cause a painful rash. In all cases, the rash disappears, but in a large number of cases, the pain persists for months or years. This pain is known as post-herpetic neuralgia (PHN).

Bhushan Akshikar, MD, GSK says, "GSK is pleased to bring Shingrix to protect India's 260 million adults above 50 years of age from shingles and its complications. Existing treatment options may not give complete relief from this pain. Vaccination is the only effective preventive option."

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2. EMA committee recommends approval of GSK's respiratory syncytial virus for prevention of LRTD caused by RSV in adults aged 60 years and older

GSK plc announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion by consensus recommending approval of GSK's respiratory syncytial virus (RSV) vaccine candidate for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults aged 60 years and older. This is the first time an RSV vaccine candidate for adults has gained a positive opinion, one of the final steps in the marketing authorisation procedure prior to approval by the European Commission.

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DRUGS: APPROVALS AND LAUNCHES

3. FDA Grants Accelerated Approval for QALSODY™ (tofersen) for SOD1-ALS, a Major Scientific Advancement as the First Treatment to Target a Genetic Cause of ALS

Biogen Inc., a leading global biotechnology company, announced that the US Food and Drug Administration (FDA) has approved Qalsody (tofersen) 100 mg / 15mL injection for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene.

This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

The ongoing phase 3 ATLAS study of tofersen in people with presymptomatic SOD1-ALS will serve as the confirmatory trial.

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4. CHMP recommends European approval of Roche's fixed-duration Columvi to treat r / r diffuse large B-cell lymphoma

Roche announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Columvi (glofitamab), for the treatment of adult patients with relapsed or refractory (R / R) diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.

Columvi has the potential to change the current standard of care in DLBCL. As well as inducing early and long-lasting responses in people with heavily pre-treated or refractory DLBCL, potentially allowing patients a treatment free period, Columvi is designed to be given for a fixed period of time so that people know when their treatment will end.

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DRUGS: DEVELOPMENT & CLINICAL TRIALS

1. Medigene reveals pivotal blood cancer therapy data

Medigene – a company concentrating on the development of T cell immunotherapies for solid tumours – has announced final phase 1 dose-escalation results from the study of its MDG1011 candidate. The therapy concerns high-risk myeloid and lymphoid neoplasms and the results will be shared at the European Society for Blood and Marrow Transplantation (EBMT) 2023 annual meeting this week. Two out of nine patients showed early response on treatment at week four and one AML patient showed complete remission at week four, but disease progression was detected at week 12. Also, one patient with multilineage MDS / MPN remained stable and did not show any progression to secondary AML throughout the 12-month trial. Four patients died from their disease, with none considered related to MDG1011.

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2. AbbVie reveals results from pivotal atogepant trial

AbbVie has announced positive data from its pivotal phase 3 ELEVATE study, studying its atogepant therapy. The ELEVATE trial met all primary and secondary endpoints. The primary endpoint was the change from baseline in mean monthly migraine days (MMDs) across 12 weeks, while the secondary targets included achieving a more than 50% reduction in MMDs. The data from the study showed adult patients in the 60mg once daily arm established a decrease of 4.20 days in their mean monthly migraine days across the treatment period. This period is significantly greater than the 1.85-day reduction observed within the placebo arm.

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3. Treatment shows strong potential for ALK-driven neuroblastoma

A Phase I study has shown significant promise in treating newly diagnosed ALK-driven high-risk neuroblastoma in paediatric patients. In the Phase I New Approaches to Neuroblastoma Therapy (NANT) trial, researchers found that lorlatinib given alone or in combination with chemotherapy was safe and tolerable in patients with relapsed / refractory anaplastic lymphoma kinase (ALK)-driven neuroblastoma. Around 30 percent of patients under the age of 18 responded to the drug. Approximately 67 percent of patients over 18 responded. Patients under 18 had a better response in combination with chemotherapy. The data showed 63 percent of patients responded to the combined treatment.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

1. US FDA issues complete response letter for Alvotech's BLA for AVT02

Alvotech, a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, announced that the US Food and Drug Administration (FDA) has issued a complete response letter (CRL) for Alvotech's Biologics License Application (BLA) for AVT02, a high-concentration biosimilar candidate for Humira (adalimumab).

The CRL noted that certain deficiencies, which were conveyed following the FDA's reinspection of the company's Reykjavik facility that concluded on March 17, 2023, must be satisfactorily resolved before the application can be approved. No other deficiencies in the application were noted by the FDA. Alvotech provided the FDA comprehensive responses to the inspection observations on April 3, 2023, and is awaiting communication from the agency assessing those responses.

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2. Ipsen reacts to NICE's Cabometyx verdict

Company disappointed by institute's failure to recommend thyroid cancer therapy for specific patient group. Ipsen has expressed its disappointed regarding the National Institute for Health and Care Excellence's (NICE) preliminary guidance which does not recommend Cabometyx – also known as cabozantinib.

NICE National Institute for Health and Care Excellence

The treatment involves patients with previously-treated differentiated thyroid cancer (DTC) which is unsuitable for radioactive iodine and has progressed after systemic treatment.

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PATENTS: NEW APPROVALS / LITIGATIONS / SETTLEMENTS

3. Chugai, TWOCELLS to terminate license agreement on investigational regenerative cellular medicine for knee chondrogenesis, gMSC1

Chugai Pharmaceutical Co., Ltd. and TWOCELLS Co., Ltd. announced to terminate the entire agreements including the license agreement concluded between the two companies on April 25, 2016, and memorandum and amendment agreement based on the license agreement (hereafter, "Agreement") for the investigational regenerative cellular medicine for knee chondrogenesis gMSC1.

Both companies will decide the effective termination date upon consultation. Upon termination of the Agreement, all domestic and foreign rights with respect to gMSC1 granted to Chugai from TWOCELLS will be returned to TWOCELLS. There will be no payment or receipt of milestone fees between the two companies.

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4. Orbital raises $270m investment for advancement of RNA medicines

Orbital Therapeutics has raised $270m in a Series A round led by ARCH Venture Partners to advance a portfolio of programmable RNA therapeutics

The initial investors were a16z Bio + Health and Newpath Partners. New investors included the Redmile Group, the Abu Dhabi Growth Fund (ADG), Exor, Invus, Moore Strategic Ventures, the iGlobe Platinum Fund Group and Casdin Capital.

Orbital will use the new funding to increase the application of RNA-based medicines for use in the fields of new vaccines, immunomodulation and protein replacement. The company is currently developing an RNA platform capable of combining well-known and upcoming RNA technologies and delivery systems. This platform can also expand the durability of new RNA therapeutics and enhance their delivery to a number of cell types and tissues.

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TECHNOLOGY / NDDS

1. Akoya Biosciences introduces PhenoCode Discovery Panels to simplify PhenoCycler-Fusion workflow

Akoya Biosciences, Inc., The Spatial Biology Company, announced the launch of PhenoCode Discovery Panels, which simplify spatial biology workflows performed on the company's PhenoCycler-Fusion platform, at the American Association for Cancer Research (AACR) Annual Meeting being held in Orlando, Florida, April 14-19, 2023.

PhenoCode Discovery Panels are designed to advance cancer research by enabling thorough interrogation of tumours and the surrounding tumour microenvironment. Each of the ready-to-use, modular panels include biomarkers that can answer key biological questions related to immune profiling, lymphocyte profiling, tissue architecture, and immune activation and proliferation.

The panels can be used on their own or combined to explore increasingly complex questions and significantly scale the "plex" of discovery in a stepwise fashion. Upfront assay development and validation time is significantly reduced, accelerating spatial discovery by 3x compared to standard workflows.

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2. Macomics reveals pivotal ENIGMAC data

Macomics – a company focused on macrophage drug discovery – has presented data demonstrating the power of its ENIGMACT macrophage drug discovery platform at the prestigious American Association for Cancer Research's Annual Meeting.

The ENIGMAC drug discovery platform is a tool specifically designed for gene-to-function studies using human macrophages. The system integrates large volume human data sets, custom cell models and proprietary human macrophage genome editing capability to establish novel targets, while also unlocking disease specific target biology.

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TECHNOLOGY / NDDS

3. Eli Lilly to sell low blood sugar drug Baqsimi to Amphastar

Eli Lilly and Company (Lilly) has entered a definitive agreement to sell its dry nasal spray, Baqsimi, to Amphastar Pharmaceuticals for a cash consideration of $500m. Lilly will receive an additional payment of $125m on the first anniversary of the completion of the deal. Amphastar is expected to make up to $450m in milestone payments based on sales of Baqsimi. The deal has received approval from the boards of directors of the two companies and is expected to complete in the second or third quarter of 2023. Baqsimi is the first and only nasally given glucagon to treat very low blood sugar, or severe hypoglycaemia, in diabetes patients.

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4. Sustained-release chemotherapy has potential for bladder cancer

A new, sustained-release chemotherapy delivery device inserted into the bladder, facilitated tumour response, a study has reported. The treatment was given to elderly patients with advanced bladder cancer who were medically unfit for standard treatment.

The intravesical device, TAR-200, provides continuous, low-dose, local delivery of gemcitabine chemotherapy. "TAR-200 was generally safe, well tolerated, and had beneficial effects on bladder cancer outcomes," commented lead author Dr Mark Tyson, MPH, of Mayo Clinic Arizona. The drug delivery device aims to limit cancer growth or progression while limiting the toxic effects of chemotherapy.

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