As CTTI Turns 10, Executive Director Looks at Accomplishments and Shortcomings

By Suz Redfearn

The Clinical Trials Transformation Initiative (CTTI)—the first consortium to pull widespread stakeholders together, including the FDA, to hash through and try to fix large-scale problems that have plagued the clinical research space—has turned 10. What has it accomplished?

CTTI Executive Director Pam Tenaerts said she's most proud of greatly elevating patient input in trials.

“One of the results of our patient engagement project was that now patients and patient advocacy groups sit at the table with us in the same numbers as sponsors and academia and as equal partners focused on writing protocols,” said Tenaerts.

Born from a collaboration between Duke University and the FDA, CTTI has completed 25 projects with the aim of increasing the quality and efficiency of clinical trials.

Jim Kremidas, industry veteran and executive director of the Association of Clinical Research Professionals (ACRP) believes that CTTI remains effective and influential because the FDA is one of its founding members.

“CTTI is unique in that they have regulatory involved,” he said.

And even though the FDA is in the room at CTTI meetings, Tenaerts said the gatherings are marked by raw honesty.

“With the environment we have created in our discussions, people feel very comfortable

see CTTI Turns 10 on page 4

CRO IQVIA Faulted by FDA for Data Inaccuracy, Quality Issues in Opioid Sales Database

By James Miessler

The FDA took vendor IQVIA to task for a discrepancy in data regarding sales of opioid drug products that the agency said could undermine forecasts used in the fight against addiction.

IQVIA collects data to measure the volume of drugs sold by manufacturers and wholesalers to pharmacies and hospitals. While conducting an analysis to estimate the amount of opioids sold in the U.S., the agency found a discrepancy in the IQVIA data that showed a more than 20 percent drop in the reported amount, expressed in kilograms, of fentanyl sold for a minimum of the past five years compared to what IQVIA's database had previously reported.

Based on a subsequent investigation and discussions with IQVIA, the FDA determined that IQVIA overestimated past data because of an error in its methods, which the agency believes resulted from the vendor utilizing the wrong weight-based conversion factors to determine the amount of fentanyl in a given unit (such as a single fentanyl patch) for a subset of prescription fentanyl products.

“While data on sales volume expressed in kilograms are used only narrowly by the FDA… we are sharing this information publicly because these data have been used in forecasts that have the potential to impact ongoing work to fight the opioid epidemic,” the agency said.

see CRO IQVIA on page 5

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May 21, 2018

A CenterWatch Publication

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Gottlieb Calls on Clinical Trial Operators to Find Ways to Enroll More Women

Clinical trial sponsors must step up their efforts to address underrepresentation of women among trial subjects, FDA Commissioner Scott Gottlieb said Wednesday during a meeting in White Oak, Maryland, to commemorate National Women’s Health Week. He cited the FDA-led Decadal Review that studied clinical trial efficacy and safety by sex for 34 drugs and five cardiovascular disease indications over a 10-year period from 2005 to 2015. The study analyzed the inclusion and exclusion criteria for five of the trials to get a clearer picture of whether such criteria affected subject enrollment. The results, Gottlieb said, indicated there were minimal gender differences in drug profiles, and that while women were well-represented in trials for hypertension and atrial fibrillation drugs and overrepresented for pulmonary arterial hypertension (PAH) drugs, they were underrepresented in trials for heart failure, acute coronary syndrome and coronary artery disease drugs. “These findings support the need for the FDA to issue a call to action to clinical investigators. In this case, the bottom line was that more work is needed to identify factors leading to under-participation of women in cardiovascular clinical trials in certain areas, notably heart failure, coronary artery disease and acute coronary syndrome,” Gottlieb said. One possible reason for under-enrollment of women subjects may be of advanced age at disease onset, Gottlieb said, indicating sponsors should look into prevalence-adjusted representation of women in cardiovascular trials across relevant age categories. On the other end of the spectrum, sponsors are often hesitant to expose new or expectant mothers, who tend to be younger women, to experimental drugs, which can be a major barrier to developing drugs for conditions that are prevalent in younger women. To correct this, the FDA is using the Medication Exposure in Pregnancy Risk Evaluation Program to model pregnant women’s responses to drugs at reduced risk, he said. Other agency efforts to remedy gender parity issues include the agency’s Diverse Women in Clinical Trials Initiative consumer awareness campaign and a planned series of webinars on recruitment and retention of women in clinical trials. The agency is also conducting several research initiatives to aid in its regulatory decision-making with regard to sex differences, he said.

U.S. Clinical Trial Begins for 3D-Printed Arms for Children

A clinical trial has been launched for children’s bionic arms produced on 3D printers, the first of its kind in the U.S., headed by researchers at the Oregon Health & Science University and Limbitless Solutions, a non-profit bionic arm manufacturer affiliated with the University of Central Florida. The clinical trial will accept 20 children to be fitted with bionic arms, who will be trained to use the implants over the span of a year. The study will test the functionality of the arms in children ages 6 to 17, evaluate its impact on their quality of life and assess how they use the arms for specialized tasks. The study will help determine the devices’ eligibility for insurance coverage, which hinges on whether or not the FDA would clear the arm for marketing.

U.K. Study Shows Potential of Electronic Health Records for More Complete Trial Results

A study by Swansea University in the U.K. demonstrated the possibilities of using anonymous, regularly collected electronic health records (EHRs) for electronic follow-up of clinical trials. With patients’ consent, data analysts can match patients to their EHRs, such as those linked in the Secure Anonymized Information Linkage (SAIL) database and access data quickly. Results showed that SAIL can help track trial participants, with long term monitoring of medical interventions and health outcomes, and new insights into population health. As a result, the cost of follow-up using routine data is potentially relatively small and does not increase with the number of participants. The original randomized controlled trial researched the effect of probiotics taken during pregnancy on asthma and eczema in a group of children at six months and then two years of age. The study’s key findings showed that the retention of children in lower socio-economic groups was improved through the use of SAIL and the electronic follow-up results were more reliable because of a reduction in bias, unreliability or inaccuracy in participants’ recollections. The electronic five year follow-up also produced new insights, particularly for asthma, which usually appears after two years of age.

FDA Warns of Lower Survival Rates for Certain Patients in Keytruda, Tecentriq Monotherapy Trials

The FDA issued an alert to clinical investigators, doctors and consumers about safety issues associated with use of Keytruda or Tecentriq as a monotherapy in oncology clinical trials. Early reviews by the FDA’s Data Monitoring Committee found patients in the monotherapy arms of two clinical trials had decreased survival compared to those receiving cisplatin- or carboplatin-based chemotherapy. All of the
Industry Briefs (continued from page 2)

FDA Releases Final Guidance on Clinical Trials for Hypogonadism

The FDA final guidance outlining clinical trial designs for hypogonadotropic hypogonadism treatments, recommending efficacy endpoints and enrollment criteria. The guidance, which was unchanged from the agency’s January draft guidance, recommends that sponsors have clinical and laboratory evidence of the condition of trial subjects, including normal thyroid function, low testosterone amounts in the morning on at least two occasions and symptoms or signs the drug aims to target. Patients should have an undamaged hypothalamus, pituitary glands and testes and the population should be specifically defined by their underlying symptoms, signs and conditions. The trials should show that the drug increases serum testosterone and contributes clinically meaningful improvement in at least one symptom or sign of hypogonadism. A responder would be a patient who has normalized testosterone concentrations (based on pharmacokinetic sampling) and also has clinically meaningful improvement in the specific symptoms or signs, the guidance advises. The agency is open to evaluating existing or modified patient-reported outcome (PRO) instruments for use in assessing disease-related symptoms or signs in men with hypogonadism but is unaware of any that are adequate for regulatory use to assess improvement in hypogonadal symptoms or signs. Improvement in biomarkers, such as changes in muscle mass, that are not established surrogate endpoints for how patients feel, function or survive, are not considered sufficient evidence of clinical benefit. For drugs that improve spermatogenesis, sponsors could establish efficacy by showing improved fertility outcomes, such as pregnancy in the patient’s partner. Changes in semen parameters—such as sperm count—are not sufficient by themselves for establishing efficacy because the intent of the drug is to improve male fertility. In addition, improved semen parameters does not ensure fertility and sperm count is only one measure of normal spermatogenesis. Drugs that worsen or do not affect spermatogenesis could still be considered effective if the sponsors show improvement in other hypogonadal signs or symptoms. The guidance does not address development programs for testosterone or testosterone esters seeking the traditional replacement therapy indication in adult males with a condition associated with endogenous testosterone deficiency or absence.

FDA Issues Draft Guidance for Antimicrobial Drugs for Cytomegalovirus

Sponsors of trials for drugs to prevent cytomegalovirus (CMV) infection in transplantation should use incidence of disease within 6 to 12 months post-transplantation as their primary endpoint, according to new draft guidance from the FDA. The guidance distinguishes between CMV prophylaxis trials in patients who have undergone solid organ transplantation (SOT) and hematopoietic stem cell transplantation (HSCT). In the case of SOT patients, the recommended primary endpoint is a clinical endpoint of both CMV syndrome and tissue-invasive CMV disease at 6 or 12 months post-transplantation, depending on the duration of prophylaxis. For HSCT patients, the recommended primary endpoint is incidence of infection or disease within six months post-transplantation. In enrolling patients in prophylaxis trials, sponsors should ensure that patients have no detectable CMV infection post-transplantation within five days before the beginning of therapy. To be enrolled in a CMV treatment trial, meanwhile, transplant recipients should have virological evidence of CMV replication. Sponsors can generally include pediatric patients in clinical trials after ensuring sufficient safety, pharmacokinetic and efficacy data are available from adults. If adult clinical trials do not give rise to any safety concerns that would preclude children from study inclusion, sponsors are encouraged to evaluate adolescents using the adult dosage. “Depending on results of the adult clinical trials, and on whether efficacy in adults can be extrapolated to pediatric patients (i.e., if the course of disease and the effect of the drug are sufficiently similar in adults and pediatric patients), either comparative or single-arm trials may be appropriate in pediatric subjects,” the guidance states. “The sponsor’s pediatric study plan should include information to support pediatric extrapolation, as needed.” Sponsors have the option to choose from a range of doses and treatment durations for phase III trials if they are unsure about the optimal regimen, or if their models indicate different doses and durations work better for different subpopulations.
Guidance for using mobile technology

Suggested ways to address the unique disadvantages associated with mobile technology.

CTTI hasn't slowed down. In 2017, the consortium issued five new sets of recommendations, many of which draw on recent advances in technology and data sciences to try to bring about improvements for clinical trials. CTTI recommendations were downloaded more than 26,000 times over the past year.

They include:
- Guidance for using mobile technology to develop viable novel endpoints for clinical trials.
- Best practices for assessing and designing registries for use in clinical trials so that the data can meet expectations for FDA review of new products.
- Actions that can be taken to strengthen the investigator site community and create an environment that sustains long-term investigator engagement.
- Guidance on planning for and making decisions about pregnancy testing in potential trial participants.
- Suggested ways to address the unique challenges of conducting pediatric antibacterial trials.

“One of the results of our patient engagement project was that now patients and patient advocacy groups sit at the table with us in the same numbers as sponsors and academia and as equal partners focused on writing protocols.”

—Pam Tenaerts, executive director, CTTI

The quick uptake of transformative recommendations over the years has surprised her, said Tenaerts, who said people on CTTI project teams will take ideas they are working on with CTTI and start running with them right away, while they are still in process.

“I had assumed companies would want to wait to have final deliverables and firm recommendations from us and then get consensus from their project teams before thinking about changing the way they’re doing things, but I was wrong,” she said.

“Through our surveys, people tell us that change often happens even before the recommendations from us are finalized.”

In its earliest days, CTTI began looking at conundrums faced in the trial monitoring process, and realized quality was suffering on the back end because not enough thought was put in at the front end of a trial during protocol design. So the group began a push for better protocol design.

“That involved making sure people focused on the things that matter in a trial, and not asking people to do too much through the course of a trial, as that will just create more errors,” said Tenaerts. “When we came out with our quality by design report, I think it represented a shift. Things changed.”

CTTI has also worked to bring significant change in the IRB space, pressing for sponsors to use one central IRB for multi-center trials rather than several local IRBs.

That has been a welcome change in the industry, said Kremidas. “The advantage of that is much faster study start-up times,” he said. “When you have multiple academic or regional IRBs, it takes so much longer.”

“We focus a lot on the why and the what, and now are working on the how in order to help people get there,” said Tenaerts.

CTTI is also creating a report about the state of clinical trials using data from clinicaltrials.gov. In July, the group is releasing its report on mobile technology, which focuses on the device side of capturing endpoints.

Tenaerts said that when CTTI got started, the plan was to affect sweeping change and then disband, but CTTI is still here.

“It’s not as if we’ve been Uber in the taxi industry. The industry we work in is so highly regulated with so much risk involved, transformation is just really hard,” she said. “We get frustrated sometimes, but if you think of how [in the field of prosthetics] we went from a wooden peg to the bladerunner that allows people to run 100 meters unbelievably fast, that was not in one fell swoop either. What we’re doing builds upon itself.”

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The agency also looked at IQVIA’s data for similar mistakes related to other controlled substances and found more data quality issues related to controlled substances with similar weight-based conversion factors—including oxymorphone and hydrocodone—raising serious concerns about the data vendor’s data and quality control.

FDA Commissioner Scott Gottlieb requested that IQVIA hire a third party auditor to review its data quality and quality control procedures for the controlled substance data the agency used. He also requested that the third party conduct an independent audit of the data quality and quality control of all IQVIA products used by the agency. The agency will be “working with federal partners on these issues and briefing members of Congress on IQVIA’s data quality issues and their potential public health implications,” the agency said. “We will provide updates to the public and our public health partners as appropriate.”

IQVIA said it has already addressed the data issues and informed clients about the error.

The company’s “internal processes had already identified the measurement conversion issue prior to the FDA’s notification,” IQVIA said. “We notified our clients about this measurement conversion issue in April of this year. Ongoing steps have been undertaken to correct this measurement conversion issue.”

HHS Final Guidance on IRB Written Procedures Clarifies Required Versus Recommended Provisions, Includes 55-Item Checklist Tool

By James Miessler

HHS published final guidance providing a checklist identifying regulatory requirements for IRB-written procedures and providing recommendations on the type of information to include.

The final guidance is largely unchanged from FDA draft guidance issued in August 2016, with the biggest change being clarifications for which provisions are required as opposed to which are recommended, according to David Borasky, vice president of IRB compliance at Copernicus Group IRB.

An IRB “that’s not sure whether or not it really has the level of detail could look at that table to identify different areas where they might want to add more detail,” Borasky said. “The most important thing is a reminder that there is a discreet set of written policies IRBs are required to have and this is a good opportunity to confirm that an IRB has those things in place.”

The final guidance will primarily be helpful for IRBs “that are unsure of whether they’ve got things covered,” Borasky told CWWeekly.

The 55-item checklist is described as a tool to help determine what information should be covered in written procedures rather than a tool for assessing compliance. It includes sections on initial and continuing review of research, verification of changes, reporting of unanticipated problems and suspension or termination of IRB approval, among other topics.

The guidance further notes that written procedures should not simply restate the regulations to which they correspond, he said.

The final guidance, issued jointly by the HHS Office for Human Research Protections and the FDA, replaces OHRP’s July 1, 2011, Guidance on Written IRB Procedures. The guidance implements provisions in the 21st Century Cures Act requiring the HHS Secretary to harmonize differences between the HHS human subject regulations and FDA’s human subject regulations.

As both OHRP and the FDA have issued several guidance documents covering more specific topics for the research process, institutions and IRBs should review the relevant documents when preparing their written procedures, the guidance states.

“We recognize that written procedures may vary among institutions and IRBs because of differences in the way organizations are structured, the type of research studies reviewed by the IRB, institutional policy or administrative practices, the number of IRBs at the institution, affiliation with an institution, and local and state laws and regulations,” OHRP and FDA said.

When preparing written procedures, IRBs should ensure they specify who carries out specific duties by title rather than by name, to avoid the need for unnecessary updates if membership or duties change, the guidance recommends. The procedures should be detailed enough to help staff understand how to do their jobs consistently while protecting subjects.
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- Treatment-Resistant Depression (TRD)
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<td>Oral therapy for infections caused by multidrug-resistant (MDR) Gram-negative pathogens, including MDR and carbapenem-resistant Enterobacteriaceae (CRE)</td>
<td>Phase I trial initiated enrolling healthy subjects from Australia</td>
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<td>Hemophilia A patients with pre-existing AAV5 antibodies</td>
<td>Phase I/II trial initiated</td>
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<td>moderate-to-severe atopic dermatitis in adolescents ages 12-17</td>
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<td>usworldmeds.com</td>
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<td>biosimilar to Epogen/Procrit (epoetin alfa) for the treatment of anemia caused by chronic kidney disease, chemotherapy or the use of zidovudine in patients with HIV infection</td>
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Lilly’s Galcanezumab Meets Primary Endpoint in Phase III Study

Eli Lilly and Company announced that galcanezumab met its primary endpoint in a Phase III study of patients with episodic cluster headache, demonstrating statistically significant differences in the reduction of weekly cluster headache attacks compared to placebo across weeks one to three of the two-month, double-blind treatment period. The episodic cluster headache study was a randomized, double-blind, placebo-controlled global trial evaluating the safety and efficacy of galcanezumab (300 mg once-monthly) administered subcutaneously compared with placebo in 106 patients with episodic cluster headache. Patients who participated in this trial had an average of 17.5 cluster headache attacks per week at baseline. The primary endpoint was the overall mean change from baseline in weekly cluster headache attack frequency across weeks one to three with galcanezumab compared with placebo. In this study, eight percent of patients treated with galcanezumab discontinued treatment during the study compared to 21 percent of patients treated with placebo. Discontinuations due to lack of efficacy occurred in two percent of patients treated with galcanezumab, compared to 14 percent of patients treated with placebo.

Concentric Analgesics Announces Positive Topline Results Post-Surgical Pain Trial

Concentric Analgesics announced topline results from its Phase Ib clinical trial for CA-008 in post-surgery. The primary objective of the clinical study was to demonstrate the safety and pharmacokinetics of CA-008, with secondary endpoints including efficacy. The study showed that CA-008, a novel, non-opioid therapeutic, was well tolerated at all dose levels compared to the control group following surgery in bunionectomy patients. The highest dose cohort of CA-008 showed statistically significant and clinically meaningful (greater than 50 percent) reductions in area under the curve (AUC) for pain intensity compared to the control group lasting up to 168 hours. The randomized, double-blind, placebo-controlled, dose-escalation study enrolled 40 patients undergoing bunionectomy with standard of care Mayo block (bupivacaine HCI 0.5 percent, up to 30 ml) and evaluated the safety of CA-008 compared to a saline control. The study was comprised of five cohorts of eight patients each, with six patients receiving CA-008 at ascending doses and two patients receiving control. Across the five cohorts, 30 patients received CA-008 across a nearly 10-fold dose range. The primary endpoints of this Phase Ib study were safety and pharmacokinetics, with various secondary endpoints including the effect on pain intensity out to two weeks post-surgery.

Regeneron Pharmaceuticals Announces Positive Results for Phase III

Regeneron Pharmaceuticals and Sanofi announced that a pivotal Phase III trial evaluating DUXIPENT (dupilumab) to treat moderate-to-severe atopic dermatitis met its primary and key secondary endpoints. In the trial, treatment with DUXIPENT as monotherapy significantly improved measures of overall disease severity, skin clearing, itching and certain health-related quality of life measures. The pivotal, Phase III, randomized, double-blind, placebo-controlled trial evaluated the efficacy and safety of DUXIPENT monotherapy in adolescent patients with moderate-to-severe atopic dermatitis. The trial enrolled 251 patients who were 12 years to 17 years of age with moderate-to-severe atopic dermatitis whose disease could not be adequately controlled with topical medications or for whom topical treatment was medically inadvisable. In total, 92 percent of these patients suffered from at least one concurrent allergic condition such as allergic rhinitis, asthma or food allergy. The primary endpoints were the proportion of patients achieving Investigator’s Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and 75 percent improvement in Eczema Area and Severity Index (EASI-75, co-primary endpoint outside of the U.S.). Results showed 24 percent of patients who received weight-based dosing of DUXIPENT every two weeks (200 mg or 300 mg) and percent of patients who received a fixed dose of DUXIPENT every four weeks (300 mg) achieved the primary endpoint - clear or almost clear skin (IGA; score of 0 or 1) - compared with 2 percent with placebo (p less than 0.0001, and p=0.0007, respectively). Patients treated with DUXIPENT had significant improvement in disease severity at 16 weeks.

BioMarin Announces First Patient Dosed in Phase I/II Study

BioMarin Pharmaceutical announced that it has dosed the first patient in a Phase I/II study (BMN 270-203) evaluating its investigational gene therapy, valoctocogene roxaparvovec, in severe hemophilia A patients with pre-existing AAV5 antibodies. The study is an open-label, single-arm, titer-escalation trial evaluating the safety and efficacy of valoctocogene roxaparvovec in AAV5+ hemophilia A patients. Patients with pre-existing AAV5 antibodies will be sequentially enrolled into two titer cohorts that will encompass the range of observed AAV5 antibody titer levels generally observed in the hemophilia population and be treated with the 6e13 vg/kg dose. The primary endpoint will evaluate safety of valoctocogene roxaparvovec in this population. Secondary endpoints include assessment of FVIII activity level, frequency of required FVIII replacement therapy, and the number of bleeding episodes requiring treatment after therapy. BioMarin is also evaluating the 6e13 vg/kg dose in GENER8-1 and a second dose of 4e13 vg/kg in GENER8-2.
Upcoming Event Highlights

Conferences

JUNE 5-6, 2018
FDA Data Integrity: For Device and Pharma Firms and Their Suppliers
Philadelphia, PA

JUNE 7-8, 2018
SOPs and Policies for the 21st Century
Philadelphia, PA

JUNE 13-14, 2018
Ensuring The Quality Connection with Your CMO
Philadelphia, PA

JUNE 19-20, 2018
Medical Device Risk Management
Raleigh, NC

[ VIEW ALL CONFERENCES ]

Training Programs

JUNE 1-31, 2018
Program Phlebotomy Training—Two Day Training
Various locations

[ VIEW ALL TRAINING PROGRAMS ]

Webinars

MAY 30, 2018
Cutting the Costs of Clinical Trial Subject Recruitment. Insights into Patient Outreach: Traditional vs. Digital
Discover outreach techniques to bring your drugs and devices to market faster and cheaper.

JUNE 14, 2018
Setting and Measuring Quality Objectives for Medical Devices
Dan O’Leary will walk you through the process and give you compliance tools to make warning letters a thing of the past.

[ VIEW ALL WEBINARS ]

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East Hanover, NJ

Clinical Documentation Specialist
Orlando, FL

Associate Director of Clinical Operations
Redwood City, CA

Clinical Trials Advisor - NIH
Rockville, MD

Senior Neuropsychologist (NC)
Milwaukee, WI

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Portland, OR

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Planned Parenthood of Southern New England
New Haven, CT

Clinical Trial Project Manager
Eli Lilly and Company
Indianapolis, IN

Clinical Study Account Executive
BBK Worldwide
Needham, MA

Clinical Research Coordinator
Segal
Charleston, SC

Clinical Site Manager
Bristol-Myers Squibb
Princeton, NJ

Clinical Research Coordinator
The University of Pittsburgh
Pittsburgh, PA

Sr. Clinical Project Manager
Syneos Health Clinical
Washington, DC

Manager-Clinical Development
Eli Lilly and Company
Indianapolis, IN

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