Proventa International’s 5th Annual
PHARMACOVIGILANCE
STRATEGY MEETING EAST COAST USA 2022

Ensuring drug safety from Clinical to Commercial

Featuring Industry Leaders and Decision Makers

Jane Carroll  
Vice President, Pharmacovigilance Operations  
Moderna Therapeutics

Fatima Bhayat  
Vice President, Patient Safety  
Amgen

Sajjan Daniel  
Vice President, Head of Drug Safety & Pharmacovigilance  
Purdue Pharma L.P.

Steve Dingman  
Vice President, Drug Safety and Pharmacovigilance  
Alkermes

Edwin Raj  
Vice President, Head of Drug Safety  
Karuna Therapeutics

Israel Gutierrez  
Vice President, Pharmacovigilance & Drug Safety  
Compugen

Richard Wolf  
Executive Director, PV Operations, Global Clinical Safety & Pharmacovigilance (GCSP)  
CSL Behring

Signal Detection
Adverse Events
Real-World Evidence
Risk Management
Artificial Intelligence
Natural Language Processing
Case Processing
Patient-Centricity
Risk-Benefit Analysis
Good PV Practice (GvP)

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STRATEGY MEETINGS!

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Proventa International’s Strategy Meetings are a completely unique experience.

Our Vision
To be a platform for creating life-saving therapies and to facilitate the creation of a completely patient centric pharmaceutical industry.

Our Mission
By encouraging key leaders and their companies to put the patient at the very heart beat of every innovation. Sharing valuable insights and strategies to assist in the discovery, development and commercialisation of life saving therapies.

Our Unique Meeting Format
- **ROUNDTABLE DISCUSSIONS**
  These interactive and informal discussions are the hallmark of the meeting. The brightest minds in the industry are brought together in 60-minute sessions that enable participants from all over the world to share ideas, challenges and lessons learned.
- **PERSONALISED AGENDA**
  Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time spent is focused and well-utilised.
- **INNOVATIVE SOLUTIONS**
  The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.
- **STRATEGIC NETWORKING**
  Strategic networking opportunities form a key benefit of the meeting. Our proven format for building and strengthening alliances to make lasting connections that benefit you.

There is a marked increase in biopharmaceutical drug approvals in recent years. The FDA alone has approved 59 new drugs in 2018, 48 in 2019 and 53 in 2020. While the FDA and other government regulatory agencies across the globe practice utmost diligence in approving drugs that are safe and have a high efficacy rate, the principle of the Weber Effect remains true and could not be ignored. Randomized clinical trial data used as a basis for drug approval could not be solely relied upon to detect possible adverse reactions for the longest possible time, representing a significantly large proportion of the global population, with varying health conditions. Further, the advent of novel drug modalities present new challenges introduced in industry. The role of Pharmacovigilance in the industry remains significant.

**WHY SHOULD YOU ATTEND THIS MEETING?**
- Bespoke networking opportunities with industry leaders to further strategic conversations to optimize existing framework and processes
- Develop industry solutions and solve immediate challenges on: Signal detection, Adverse events/case processing, AI A Natural Language Processing, Patient Centricity and Real-world evidence, Risk Management and Technology-Driven Pharmacovigilance
- Collaborate with solution providers to discover latest tools & techniques to enhance PV operational excellence
- Gain practical insights through real-world case studies
- Explore revolutionary concepts and new practices to optimize signal detection
- Our unique closed-door roundtable format enables 10-15 participants to discuss ideas, concepts, practical studies and challenges within the Pharmacovigilance community
- Different to a conference, this Strategy Meeting allows you to choose and participate on topics that are directly relevant to you and your immediate work
- Exclusively <invitation-only> for C-level, Senior Vice Presidents, Vice Presidents, and other top level executive facilitators from leading pharma and biotech companies

**SENIORITY OF ATTENDEES**
- Director Level: 31.3%
- Manager: 14.3%
- Team Lead: 12.1%
- PV Specialist: 8.5%
- CT Specialist: 7.8%
- Department Head: 6.5%
- President / VP: 6.2%
- Scientist: 4.6%
- C-Level: 3.9%
- Other: 3.9%

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Facilitator Faculty

Vijay Bhargav
Vice President – Lifecycle Safety
IQVIA

Barry Mulchrone
Senior Director and Head
IQVIA
Pharmacovigilance Oversight and Analytics

Vivek Kalagara
CEO
Datafoundry AI

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Alkermes

Israel Gutierrez
Vice President, Pharmacovigilance & Drug Safety
Compugen

Barbara Morollio
Executive Director, Head of Global Safety Science, DSPV
Ultradynx

Ajinkya Pawar
Director Real-World Investigator
Sanofi

Edwin Raj
Vice President, Head of Drug Safety
Karuna Therapeutics

Jeff Roncal
Vice President & Head of Safety
Jounce Therapeutics

Richard Wolf
Executive Director, PV Operations, Global Clinical Safety & Pharmacovigilance (GCSP)
CSL Behring

How Has Our Strategy Meetings Benefit The Life Science Industry

This was a very important insightful event and I have few takeaways messages/practices which I will be implementing on my current and future projects.”
Jean-Pierre Metabanzoulou - Senior Director, CMC & RA, Acasti Pharma

I always find these meetings to be useful. The format is unique and lends itself to the on-line experience.”
Mark Tebbe - Co-founder and Chief Technology Officer, Quench Bio

Who Should Attend?

- Drug Safety Leaders
- Qualified Person for Pharmacovigilance (QPPV)
- Drug Safety Inspectors
- Medical Affairs Officers
- Clinical Safety Leaders
- Risk Management Officers
- Patient Safety Leaders
- Drug Safety Evaluation Officers
- Safety Data Analysts
- Safety Science Specialists
- Adverse Reporting
- Product Safety Surveillance Officers

- Quality Assurance Specialists
- Patient Access Program Leaders
- Pharmacoepidemiologists
- Pharmacovigilance Informatics
- Medical, Regulatory, & Quality Officers
- Data Science and Advanced Analytics
- Late-stage development leaders
- PV Audit / Analytics

Pharmacovigilance Strategy Meeting
East Coast USA 2022
16 May
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**Lead Sponsor**

IQVIA is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry. IQVIA creates intelligent connections to deliver powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients. Using global experts in over 100 countries, dedicated cloud-based safety technology, proven processes, advanced analytics including the market-leading NLP platform, IQVIA provides customers with improved compliance performance at lower cost, better predictive planning and visibility across the complete compliance landscape.

**Associate Sponsor**

Datafoundry is a research-driven AI technology company enabling the delivery of safe and innovative treatments in a patient-centric manner. Our technologists and researchers in Data Science, Medical NLP, Deep Learning models and Cloud/Edge Computing help customers innovate safer, faster and better. Datafoundry’s AI solutions include mSafety for Safety Management - Pharma/Cosmetics/Devices/Nutra, mLiterature - Literature Review, Meta Analysis, Label Review, Clinical Document Authoring, HEOR, IDMP Compliance, and Data Digitization & Analytics for Clinical, Supply Chain and Sales data. The Datafoundry Health 4.0 Cloud SaaS solutions deliver value to our customers through seamless integration with existing technology systems.

**Thought Leaders**

- insife
- Explic8

**Co-host Sponsor**

biologit

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Global Sponsorship Opportunities

Proventa’s end-to-end consulting division gather real-time business intelligence on the industry’s needs, challenges, budgets and investment areas. We combine this information with your specific needs to enhance your business development strategy. With the wealth of intel we provide, Proventa guarantees tangible results for your business within twelve months of the event.

For Sponsorship Opportunities please contact:

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How it Works?
Real insights are shared in conversations, not lectures. That’s why our unique **roundtable** format guarantees real learning and ensures you only attend discussions that deliver value to you.

Join as many as four roundtable discussions, each with up to 20 other subject experts, networking with top-level peers in an informal, relaxed and sociable environment.

Simply follow the steps below to select your roundtable discussions and we’ll create your own personalised agenda for the day:

1. **EXPLORE THE FULL AGENDA**
   - Select which roundtable discussions you would like to join. Our sessions are divided among 6 themed tracks for easy selection - you can choose to join any session you like.

2. **COMPLETE YOUR SCHEDULING FORM**
   - Select your preferred roundtable discussion for each time slot. We will send this form out via email a few weeks before the event - be sure to get your first choice by completing the form quickly.

3. **ENJOY YOUR PERSONALISED EXPERIENCE**
   - Join your selected roundtable discussions on the day by following the links we send you. We’ll even send personalised calendar invitations so you don’t miss a single minute.

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**Agenda at a Glance**

*Pharmacovigilance Strategy Overview 16th of May, 2022 – Cambridge, Boston - Le Meridien Hotel*

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<tbody>
<tr>
<td>08:00 - 08:30</td>
<td>OPENING KEYNOTE PRESENTATION/PANEL</td>
<td>AI-driven Business Transformation – Realizing the Promise</td>
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<td>08:30 - 09:00</td>
<td>REGISTRATION AND WELCOME</td>
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<td>09:00 - 10:00</td>
<td>DISMISSING FALSE SIGNALS EFFECTIVELY AND RAPIDLY WITHOUT COMPROMISING DRUG SAFETY</td>
<td>TACKLING THE CHALLENGES IN AI REPORTING METHODOLOGIES AND DATA ANALYSIS IN COMBINATION PRODUCTS/ THERAPY</td>
<td>THE FUTURE OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE</td>
<td>DECREASING RISKS AND IMPROVING STRATEGIES FOR PATIENT SAFETY WHILE USING RWE/RWD IN REGULATORY DECISIONS</td>
<td>ASSESSING THE BENEFT-RISK PROFILING OF DRUGS THROUGHOUT ITS LIFECYCLE</td>
<td>DISMISSING FALSE SIGNALS EFFECTIVELY AND RAPIDLY WITHOUT COMPROMISING DRUG SAFETY</td>
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<td>16:30 - 17:00</td>
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Event Day

OPENING KEYNOTE PRESENTATION/PANEL

8:30 – 9:00 EST
Al-driven Business Transformation – Realizing the Promise
- The Promise of AI innovation in making drugs safer and reach patients faster
- Current approaches & challenges
- Best practices in AI-driven process automation and innovation

Vivek Kalagara
CEO
Datafoundry AI

KEYNOTE PRESENTATION

13:00 - 13:30 EST
(Topic TBC)

INSAFE

PANEL DISCUSSION

16:30 - 17:00 EST
Embracing a Technology Driven Pharmacovigilance for Future Demands
- Advancing Pharmacovigilance systems through technology: Reviewing the current technologies that can be used in PV
- Analyze the challenges and opportunities in using these technologies

TRACK 1: SIGNAL DETECTION

The process of actively searching for and identifying safety signals from a wide array of sources remains a big challenge for PV experts. Hence, the problem of detecting unknown and unpredictable safety signals is still relevant today. This track focuses on discussing effective tools that could help in enhancing and managing signal detection and ways to dismiss false signals rapidly.

09:00 – 10:00 EST
ROUNDTABLE 1:
Identifying highly effective tools to be used in enhancing, managing, and evaluating signal detection to achieve robust pharmacovigilance
- Discussing the recent instruments that can be employed by pharma/biotech companies to help bridge gaps in signal report sources. Determining the most suitable technique to use in screening the data gathered
- Evaluating developments, challenges and future needs in methodologies towards signal detection and assessments
- Overcoming struggles in signal assessment to include different modalities and biologics

Sajjan Daniel
Vice President, Head of Drug Safety & Pharmacovigilance
Purdue Pharma L.P.

11:00 – 12:00 EST
SOLUTION FOCUS ROUNDTABLE 2:
Dismissing false signals effectively and rapidly without compromising drug safety

13:30 – 14:30 EST
SOLUTION FOCUS ROUNDTABLE 3:
New responsibilities in the signal management process during the COVID19 era

15:30 – 16:30 EST
ROUNDTABLE 4:
Using regulatory intelligence in pharmacovigilance to aid in anticipating possible adverse events
- Factors to consider in outsourcing monitoring services
- Tackling the changes in Good Pharmacovigilance Practice (GvP) that were implemented during the pandemic
- Adjusting internal Key Performance Indicators (KPI) in terms of pharmacovigilance systems to current situations
- Adjusting the signal detection plan to current technologies

Israel Gutierrez
Vice President, Pharmacovigilance & Drug Safety
Compugen

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**TRACK 2: ADVERSE EVENTS/ CASE PROCESSING**

As a vital activity in Pharmacovigilance, guaranteeing the highest quality of safety data processing is pivotal. Employing AI, ML, and even blockchain technologies in case processing could benefit pharmaceutical and biotech companies in coming up with correct analysis and timely corrective actions.

**09:00 – 10:00 EST**

**ROUNDTABLE 1:** Tackling the challenges in AE reporting methodologies and data analysis in combination products/therapy

Background: The granting of EUA to use Baricitinib and Remdesivir for Covid-19 treatment poses yet another challenge in the Pharmacovigilance field in terms of determining adverse events - with Baricitinib a relatively new drug and Remdesivir a repurposed drug, integrated to combat a virus that is still not yet fully known

- Difference of FDA and EMA in terms of combination products guidelines
- Effectively bridging the gap between randomized clinical trial data and healthcare data to apply in combination product usage
- Ways to recognize possible effects of drugs on patients taking combination drugs or therapy and the models that can be used to predict adverse effects of drug-drug interaction

**Steve Dingman**  
Vice President, Drug Safety and Pharmacovigilance  
Alkermes

**11:00 – 12:00 EST**

**SOLUTION FOCUS ROUNDTABLE 2:** Discovering endless frontiers in attaining Quality Case Processing (Topic TBC)

- Ensuring the highest quality in case processing
- Common errors in case processing
- Ways to address these errors
- Taking advantage of electronic medical records and reimbursement information to complement FAERS (FDA Adverse Event Reporting System)
- Tackling the need for competence development of staff

**Vijay Bhargav**  
Vice President – Lifecycle Safety  
IQVIA

**13:30 – 14:30 EST**

**SOLUTION FOCUS ROUNDTABLE 3:** Using AI/ML and Blockchain technologies in Pharmacovigilance

- AI case intake, triage, signal detection and narratives
- Blockchain-based ADR collection and tracking
- Predictive ADR models to build safety profiles of drugs/ingredients

**Jane Carroll**  
Vice President, Pharmacovigilance Operations  
Moderna Therapeutics

**15:30 – 16:30 EST**

**ROUNDTABLE 4:** Best practices to modernize our approach to case management and handling

- Covid-19 vaccine manufacturers have received unprecedented adverse event volume globally and have had to quickly adapt a ‘one size does NOT fit all’ mentality
- Moderna has used a mix of workflow automation and prioritization tools to manage case processing activities paired with state of the art AI tools

**Steve Dingman**  
Vice President, Drug Safety and Pharmacovigilance  
Alkermes
TRACK 3: AI & NATURAL LANGUAGE PROCESSING
Consolidating human linguistics and technology are currently being explored through AI. Recognizing where it can be applied, extracted, and how data can be interpreted using AI tools will greatly enhance PV process.

09:00 – 10:00 EST
ROUNDTABLE 1: The Future of Artificial Intelligence in Pharmacovigilance
- Identifying tasks, methodologies and data sets where AI can be applied
- Discussing the possible hiccups in embracing AI in PV and how to overcome them
- Offshoring vs outsourcing: Tapping the best option for PV global units

Richard Wolf
Executive Director, PV Operations, Global Clinical Safety & Pharmacovigilance (GCSP), CSL Behring

11:00 – 12:00 EST
SOLUTION FOCUS ROUNDTABLE 2: Harnessing the power of AI to deliver optimal RWE/RWD solutions
- Using AI to generate RWE/RWD in specific use cases – disease prevalence, safety
- ML models to help manage the data collection, classification and analytics
- AI-assisted Literature Review combined with RWD analytics to support Clinical Study Outcomes

13:30 – 14:30 EST
SOLUTION FOCUS ROUNDTABLE 3: Using AI to effectively manage the increasing volume and complexity of safety workloads (Topic TBC)

15:30 – 16:30 EST
ROUNDTABLE 4: Integrated Risk Management Plans to adhere to current guidelines and global standards
- Adjusting to global regulatory guidelines and measures into Risk Management Plans
- Addressing regulatory challenges across global PV management
- Discussion on the practical lessons learned during the pandemic that can be incorporated in the Risk Management Plans

TRACK 4: PATIENT CENTRICITY & REAL-WORLD EVIDENCE
Bringing safety to patients rather than bringing patients to safety is the ultimate goal in Pharmacovigilance. Some topics under this track include increasing patient engagement through patient support programs and factors in achieving patient-centric approach in post-marketing surveillance.

09:00 – 10:00 EST
ROUNDTABLE 1: Decreasing risks and improving strategies for Patient Safety while using RWE/RWD in Regulatory decisions

Ajinkya Pawar
Director Real-World Investigator
Sanofi

11:00 – 12:00 EST
SOLUTION FOCUS ROUNDTABLE 2: Revised approaches to ensure stable quality and reliability

13:30 – 14:30 EST
SOLUTION FOCUS ROUNDTABLE 3: Establishing Patient Support Program to increase patient engagement
- Factors to consider in developing a Patient Support Program
- Establishing and handling data security from Patient Support Program to Marketing Authorization Holders
- Outlining a roadmap towards advancing Patient Support Program to include Covid-induced transformations

15:30 – 16:30 EST
ROUNDTABLE 4: What are the key factors in achieving patient-centric approach in post-marketing surveillance?
- Using social media to intensify patient engagement and create drug safety awareness
- Exploring possible collaborations in using a Mobile healthcare management system in to reach out to patients
- Considering other digital health technologies to intensify RWE collection and patient centricity and discussing the advantages and limitations for each one?
Event Day

**TRACK 5: RISK MANAGEMENT**

Establishing a healthy benefit-risk balance of drugs throughout its lifecycle by continuously assessing a drug’s benefit-risk analysis is a major component in Pharmacovigilance. Likewise, safety science and risk management in rare diseases is a hot topic that will be discussed under this track.

09:00 – 10:00 EST

**ROUNDTABLE 1:** Assessing the Benefit-Risk profiling of drugs throughout its lifecycle

- Integrating patient perspective in assessing drug risks in post-marketing
- Methods to quantify the risk
- Techniques to weigh risk in individual ADR
- Points to consider when assessing drug benefits during post-marketing

Fatima Bhayat
Vice President, Patient Safety
Amgen

11:00 – 12:00 EST

**SOLUTION FOCUS ROUNDTABLE 2:**

What are the future approaches for risk management plans, strategies and new risk-benefit analysis?

13:30 – 14:30 EST

**SOLUTION FOCUS ROUNDTABLE 3:**

Addressing regulations and challenges that can accommodate all national requirements in a global organisation

15:30 – 16:30 EST

**ROUNDTABLE 4:**

Safety Science and risk management in rare diseases

Barbara Morollo
Executive Director, Head of Global Safety Science, DSPV
Ultragenyx

**TRACK 6: EVOLVING PHARMACOVIGILANCE**

Abrupt disruptions in the pharmaceutical operations due to the pandemic brought transformations in the Pharmacovigilance system. This track features discussions on process automation and digital shifts, plus the latest innovations and approaches in signal management and other PV activities.

09:00 – 10:00 EST

**ROUNDTABLE 1:**

Advantages and disadvantages of the signal validation process

Jeff Roncal
Vice President & Head of Safety
Jounce Therapeutics

11:00 – 12:00 EST

**SOLUTION FOCUS ROUNDTABLE 2:**

What are the latest approaches for leveraging technology to overcome key challenges? (Topic TBC)

Barry Mulchrone
Senior Director and Head, IQVIA Pharmacovigilance Oversight and Analytics

13:30 – 14:30 EST

**SOLUTION FOCUS ROUNDTABLE 3:**

Various methodologies to enhance patient engagements

- Innovative approaches to gauging early site interest and finding the best sites for each trial
- Approaches to partnering with a broader range of community-based sites
- Insights from community site leaders who successfully partnered with large, global sponsors to enroll underserved patients

15:30 – 16:30 EST

**ROUNDTABLE 4:**

Addressing the challenge of extracting useful data from global databases and other sources for faster, more efficient, and compliant case processing

- Smart ways of handling volume of data, integration, data transformation rate, and validity
- Identify tools or platforms that could support data analytics
- Data merging techniques and methods useful for AE/case processing

Edwin Raj
Vice President, Head of Drug Safety
Karuna Therapeutics

Please contact: info@proventainternational.com to register your interest

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**Venue**

Le Méridien Hotel - Cambridge, Boston

Le Méridien Cambridge-MIT’s elegant guest rooms and suites offer a place of luxurious sanctuary and unmatched comfort.

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For more details email: [emilia@proventainternational.com](mailto:emilia@proventainternational.com)

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**OUR FACE-TO-FACE MEETING IN MAY & JUNE 2022**

*Strategy Meeting Boston & San Francisco, USA and London, Europe*

### San Francisco - US West Coast

- **MAY 09 MON**  
  **Drugs Discovery Biology**  
  Drug Discovery Biology Strategy Meeting 2022  
  Westin St. Francis San Francisco on Union Square

- **MAY 11 WED**  
  **Clinical Operations**  
  Clinical Operations Strategy Meeting 2022  
  Westin St. Francis San Francisco on Union Square

### Boston/Cambridge MA - US East Coast

- **MAY 16 MON**  
  **Pharmacovigilance**  
  Pharmacovigilance Strategy Meeting 2022  
  Le Méridien Cambridge

- **MAY 18 WED**  
  **Clinical Operations**  
  Clinical Operations Strategy Meeting 2022  
  Le Méridien Cambridge

- **MAY 23 TUE**  
  **Bioinformatics**  
  Bioinformatics Strategy Meeting 2022  
  Le Méridien Cambridge

- **MAY 25 THUR**  
  **Medicinal Chemistry**  
  Medicinal Chemistry Strategy Meeting 2022  
  Le Méridien Cambridge

### London - Europe

- **JUN 07 TUE**  
  **Bioinformatics**  
  Bioinformatics Strategy Meeting 2022  
  Radisson Blu Hotel London Stansted Airport

- **JUN 09 THUR**  
  **Medicinal Chemistry**  
  Medicinal Chemistry Strategy Meeting 2022  
  Radisson Blu Hotel London Stansted Airport

- **JUN 15 WED**  
  **Clinical Operations**  
  Clinical Operations Strategy Meeting 2022  
  Radisson Blu Hotel London Stansted Airport

- **JUN 16 WED**  
  **Pharmacovigilance**  
  Pharmacovigilance Strategy Meeting 2022  
  Radisson Blu Hotel London Stansted Airport

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**Ensuring drug safety from Clinical to Commercial**

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