

USP Stakeholder Engagement:

Better Standards Through Strengthened Engagement

Global Standards and
Science Division

April 11, 2022



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Stakeholder Engagement

Jennifer Devine, J.D.

Senior Vice President

Documentary Standards & Compendial Policy

Global Standards and Science Division

Collaborating to achieve our mission



**USP Experts &
Convention Members**



**Quality
medicines**



**Scientific,
healthcare stakeholder
communities, including
industry & academia**

**Global regulatory
entities and other
pharmacopeias**



2021-2022 Stakeholder Engagement Planning Committee



Prescription/Non- Prescription

- ▶ Danita Broyles, Harmony Biosciences, **Chair**
- ▶ Kay Marie Whiten, Kay M Whiten LLC, **Vice-Chair**
- ▶ Anne Cook, Eli Lilly and Company
- ▶ Shane Gassman, Dechra Veterinary Products
- ▶ Eliangiringa Kaale, Muhimbili University Of Health and Allied Sciences
- ▶ Minghui (Sam) Li, University of Tennessee Health Science Center
- ▶ Jigar P. Mehta, Alembic Pharmaceuticals Ltd.
- ▶ Pallavi Nithyanandan, U.S. FDA
- ▶ Jennifer Putnam, Perrigo
- ▶ Janeen SkutnikWilkinson, BIOGEN
- ▶ Hantz Tattergrain, Pfizer
- ▶ Jose Zayas, Zaycor Industries Corporation

- ▶ **To Broaden the reach of applicants, we held a Call for Candidates**
 - Over **65** applications from various industries:
 - Associations, Drug Manufacturers (large and small), Pharmacy, Government, and Academia
 - 60% new members

- ▶ **SEPC Membership:**
 - Total Membership; 12 (including FDA)
 - Industry Groups/Trade Association Members: 6
 - Group Diversity Expansion: Inclusive of academia, veterinary health, Ex-US members

The journey of a standard is not a straight path



Engagement around knowledge is an essential thread



Focus on problem solving

- **Seek** active and continuous input
- **Iterate** from exploratory stage to full utilization
- **Convene** the right people, at the right time
- **Utilize** collaboration platforms to best gather stakeholder insights and discussion
- **Create** “fit-for-purpose” approaches to leverage stakeholders’ expertise
- **Enhance** accessibility of USP’s knowledge & resources
- **Ensure** transparency of engagement

Bringing it all together



Early Exploratory

Bring community together
Robust dialogue on public health and quality topics

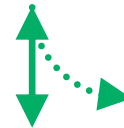
Goal ▶ Advance knowledge, identify challenges



Pre-Compendial Shaping the Standard

More structured engagement
Build consensus and alignment
Identify gaps and resolve issues

Goal ▶ PF-ready standard reflecting all major input



Post-Publication Implementing the Standard

Build awareness
Provide education, training, tools
Seek feedback on standard

Goal ▶ Adoption and use of standard, input on future revisions



Compendial Finalizing the Standard

Traditional compendial processes and policies, with formal notice and comment

Goal ▶ Official Standard



Before moving to next stage, evaluate whether **standard** is the appropriate solution for problem we are trying to address. May mean going back to previous phase for further discussion.



At each stage, consider alternative paths to success. May include hand-off to other organization, dissemination of work through publication, etc.

Maximizing our Impact



Continue to

- Focus on quality standards and solutions
- Preserve formal compendial process
- Continue engagement with the companies, industry groups, compendial liaisons
- Maximize public health together

Focus more ...

- Problems and solutions
- Move towards timely engagement and earlier
- Transparency
- Disseminate information

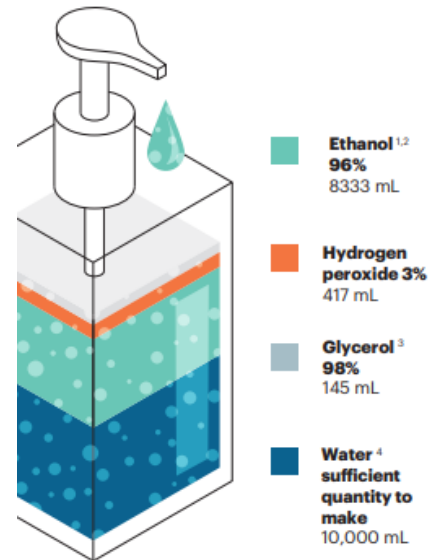
Examples of Engagement



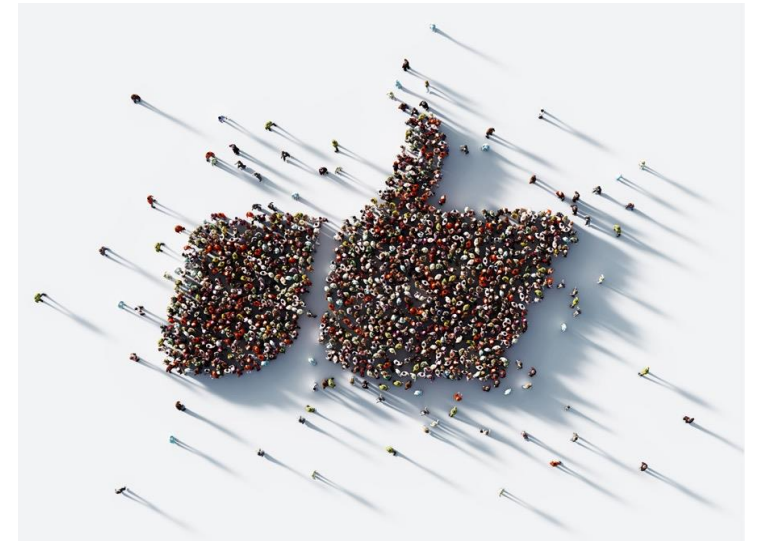
Virtual



Open Forums



Knowledge Hubs



2 Leveraging Virtual Engagements

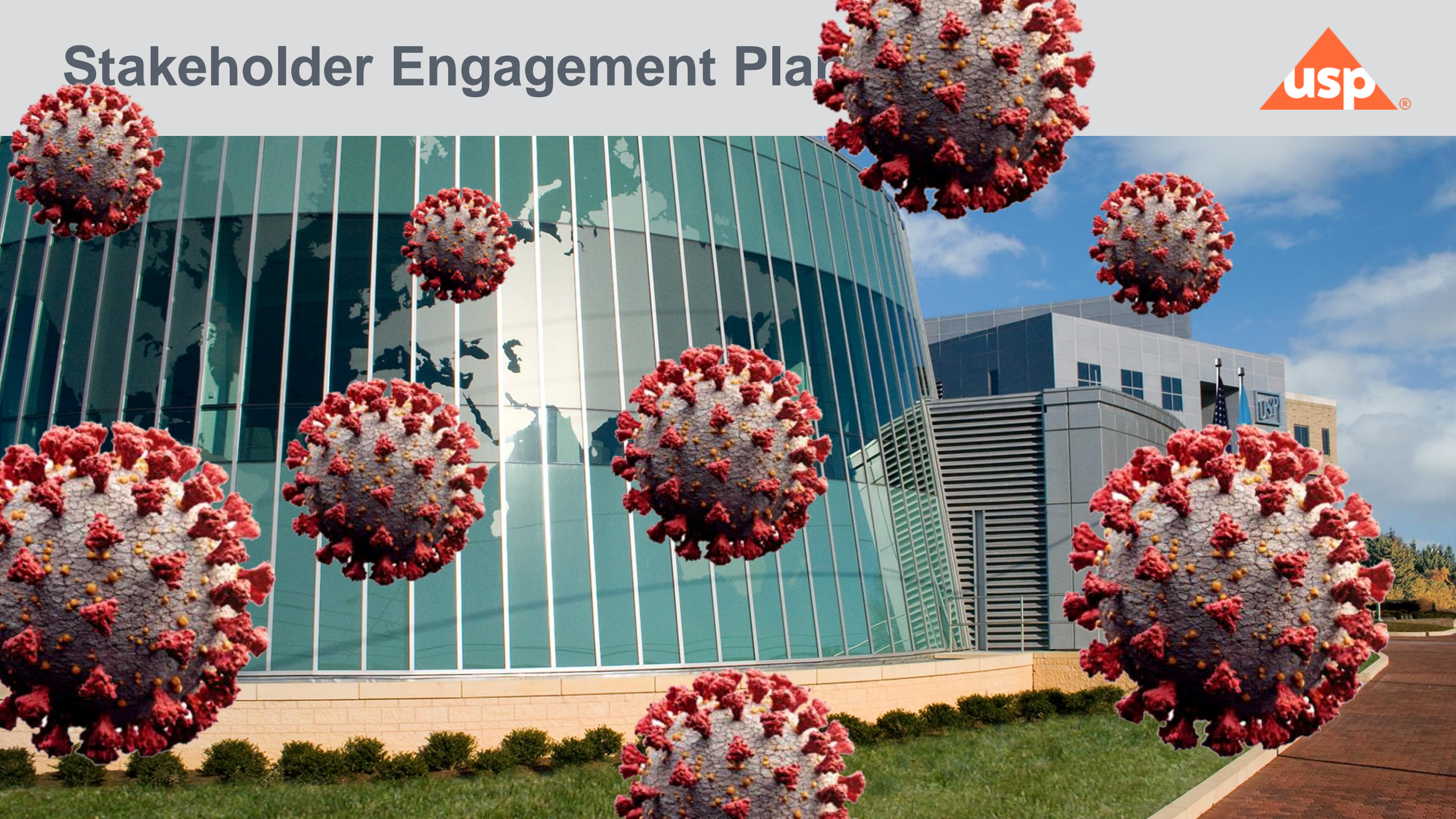
Edwin Gump, Ph.D.

Vice President

Small Molecules

Global Standards and Science Division

Stakeholder Engagement Plan



Small Molecules; Nov 2020

- ▶ Obtain further stakeholder feedback on a variety of possible approaches to addressing Reporting Thresholds in monographs
 - Due to the complexity of the topic, it was felt that a Webex live in person round table event would be difficult.

- ▶ Asynchronous format allowed invitees to participate any time during the event that was convenient for them
 - Eliminated time zone barriers
 - Participants interacted on virtual discussion boards posting their thoughts and responding to those of others

Virtual Roundtable (Reporting Thresholds)



Small Molecules; WebEx-based, June 2021

- ▶ Our purpose was to propose a specific approach to addressing Reporting Thresholds in monographs and gather stakeholder feedback
 - In this case, USP felt that the topic was directed enough that it would be possible to conduct an effective round table using a virtual on-line meeting format
- ▶ Successful virtual Round Table meetings require adopting a format that is best fit for purpose
- ▶ **Thanks to COVID, USP has been forced to rethink our strategies around engagement and develop new tools.**

3 Stakeholder Engagement Open Forums

Danita Broyles, M.S.

Associate Director Quality Assurance
Harmony Biosciences

Stakeholder engagement: Open Forums



Effective new engagement tool for sharing information and collecting stakeholder input

- ▶ Open Forums are virtual meetings on a timely topic that complement other flexible approaches
- ▶ Includes an overview of the topic followed by Q&A
- ▶ Facilitated discussion enables impactful dialog
- ▶ Six events held in this cycle to date

Open Forum

Manufacturing Alcohol to Combat a Public Health Emergency: Insights on Regulatory and Quality Requirements

January 27, 2021 | January 28, 2021

Open Forum

The Future of Public Commenting

March 29, 2022

Open Forum

Impurities and Contaminants in Dietary Ingredients and Dietary Supplements

April 21, 2022



<https://www.usp.org/get-involved/provide-input/stakeholder-forums>

Open Forum - Testing for Methanol

Engagement from industry, regulators and USP on emerging issues

- ❑ Virtual Open Forum that was created to **provide information** to stakeholders concerning an **urgent** emerging public health need
- ❑ **Requested by numerous stakeholders in the alcohol industry**
- ❑ Up to 200+ individuals from the alcohol industry, regulators, and USP
- ❑ **Regulators presented on current rules, guidance, and concerns**
- ❑ Compendial requirements discussed and explained
- ❑ **Industry presented their needs, desires, and impact**



Thank You



Empowering a healthy tomorrow

A large, light blue graphic on the left side of the slide, featuring a circle with a stylized number '4' inside. The '4' is formed by a vertical line on the left, a horizontal line at the top, and a vertical line on the right that extends below the horizontal line.

Knowledge Hub Pilots Update & Look Ahead

Naiffer Romero, M.Sc.

Scientific Affairs Senior Manager

Nitrosamines Community Manager



- ▶ Unleashing the power of online communities
- ▶ Democratization and inclusion of knowledge
- ▶ Engineered for asynchronous, hybrid work structures
- ▶ Increase and accelerate early scientific knowledge exchange in select topics
- ▶ Members define, USP hosts

Nitrosamine Exchange Community



Nitrosamine Exchange Knowledge Community



Nitrosamines Exchange
A knowledge based community for all-things Nitrosamine

English (US)

Featured Topics

- Confirmatory Testing ... // 19d
Publications review on Nitrosamines (Analytical) 2022
- New Scientific Knowle... // 5d
EMA Nitrosamine Implementation Oversight Meeting Highlights Mar'22
- How-To // 5d
Translate and post in other language -NEW
- New Scientific Knowle... // 18d
AZIDO Impurities Topic

Current Nitrosamine Landscape in Japan?
New Scientific Knowledge & Development

English (US)

Latest **Top** **Topic**

Yosukemino Regular 2 9d
関西医薬品協会 (Kansai Pharmaceutical Industries Association) の会報 (2022年3月号) から、ニトロソアミンワーキングチームの情報を共有します。

- Q&Aがまだ発出されていないため、その状況を確認した。Q&Aは何回かに分けて順次発出される予定であるが、1回目のQuestionについては、ワーキングチームでレビュー中とのことであった。全体のQ&Aがいつごろまでに発出されるかわからない状況になっている。Q&Aが発出されず、タイムスケジュールが走っている状態である。
- 行政からQ&A案に対するコメントがあり、ワーキングチームで検討中である。2月下旬~3月上旬に最終確認後に、Q&Aを発出予定。

google翻訳の英語訳を見ながら、日本語を原文から少し変えています。

以下は私のコメントです。
多くの製薬企業や行政の方々は、一刻も早く日本国内のニトロソアミンQ&Aが公開されることを心待ちにしていますが、一方でどのような質問が含まれているのかは知られていません。
会報にQ&A発出の予定が記載されていますが、これまで予定通りに進捗しておらず、実際にいつ頃に発出されるかも不明です。

If you want to translate Japanese to your language, please click the global icon like earth at the bottom right.

Translated from ja by Google

Information on the Nitrosamine Working Team will be shared from the newsletter (March 2022) of the Kansai Pharmaceutical Industries Association.

- Since the Q & A has not been issued yet, we confirmed the situation. The Q & A is scheduled to be issued in several batches, but the first Question is being reviewed by the working team. It is not known when the entire Q & A will be issued. The time schedule is running without Q & A being issued.
- The government has commented on the Q & A proposal, and the working team is considering it. Q & A will be issued after the final confirmation from late February to early March.

Join <http://nitrosamines.usp.org>

- ▶ **It is** supporting USP's efforts to increase early connectivity and engagement with *SMEs*
- ▶ **It is** a monitored community platform for scientific knowledge exchange on all-things nitrosamine
- ▶ **It is** a way for USP to incubate, learn and share knowledge/resources with a global community

- ▶ **It is not** focused on proposed USP General Chapter <1469> *Nitrosamine Impurities*
- ▶ **It is not** a social media channel, **It is** a professional network (just online)
- ▶ **It is not** a substitute for public comment in PF or compendial processes
- ▶ **It is not** a venue to influence or change policy
- ▶ **It is not** a tool for every topic

In almost 12 months ...



An opportunity for scientists to discuss science

- ▶ 80,000 page views
- ▶ 800 members, 70 countries
- ▶ Multiple roles
 - Process Chemist
 - Safety & Toxicology
 - Analytical Chemist
 - Regulatory
- ▶ Various Industries
 - Manufacturers (API, Excipients, Innovators & Generics)
 - Packaging & Chemical Suppliers
 - Consultant Services (Toxicology)
 - Technology Providers

Mutagenic Impurities Strategies for Identification and Control - now published

■ Guidance, Documents, Resources
Excipients, Packaging, Drug_Substance_APis, Manufacturing, Solvent_Water



Nitrosamine impurities in drug product specification

■ Limits of Nitrosamines



'Live' Nitrosamine Conversation - ANVISA new guidance 23 days ago

■ Events / Workshops / Webinars Live-Conversations



N-nitroso-propranolol?

■ Nitrosamines in the News



Azithromycin - presence of N-Nitrosamines

■ Nitrosamines in the News Manufacturing



Nitrosamine Implementation Oversight Group (NIOG) - second meeting with pharmaceutical industry

■ Events / Workshops / Webinars



What have we learned so far?



Scientists discussing science.

- ▶ You learned it here first!
- ▶ Rich engagement, organic growth with an inclusive discussion
 - Community Manager is essential for community
- ▶ What can we learn from each others' pain points?

Thank You



The standard of trust