


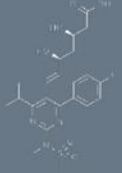
What is a Quality Solution Sheet? (QSS)



Small Molecules

Rosuvastatin

Quality Solutions
Therapeutic Category: Antihyperlipidemic



USP can support your development and manufacturing activities on Rosuvastatin-based medicines with these existing and upcoming standards.

Official and Proposed Documentary Standards and Associated Physical Materials

MONOGRAPH 1	
ROSUVASTATIN CALCIUM Status: Official. Official date: MAY 1, 2020	
USP Rosuvastatin Calcium RS	1606015
USP Rosuvastatin Enantiomer RS	1606059
USP Rosuvastatin Related Compound A RS	1606026
USP Rosuvastatin Related Compound B RS	1606037
USP Rosuvastatin Related Compound C RS	1606048
PHARMACEUTICAL ANALYTICAL IMPURITY(ES)†	
Rosuvastatin Ketone	1A00050
Rosuvastatin Lactone	1A01200
ROSUVASTATIN CALCIUM Status: Published in PF 47 (4), JULY 1, 2021*	
USP Rosuvastatin System Suitability Mixture RS Coming Soon	1606004
USP Rosuvastatin Calcium RS	1606015
USP Rosuvastatin Enantiomer RS	1606059
USP Rosuvastatin Related Compound A RS	1606026
USP Rosuvastatin Related Compound B RS	1606037
USP Rosuvastatin Related Compound C RS	1606048
PHARMACEUTICAL ANALYTICAL IMPURITY(ES)†	
Rosuvastatin Ketone	1A00050
Rosuvastatin Lactone	1A01200

* Monographs in Pharmacopoeial Forum (PF) online are not official and may not become official, so they are not suitable to demonstrate compliance.

MONOGRAPH 2	
ROSUVASTATIN TABLETS Status: Official. Official date: JUNE 1, 2019	
USP Rosuvastatin Calcium RS	1606015
PHARMACEUTICAL ANALYTICAL IMPURITY(ES)†	
Rosuvastatin Ketone	1A00050
Rosuvastatin Lactone	1A01200
ROSUVASTATIN TABLETS Status: Published in PF 47 (4), JULY 1, 2021*	
USP Rosuvastatin System Suitability Mixture RS Coming Soon	1606004
USP Rosuvastatin Calcium RS	1606015
PHARMACEUTICAL ANALYTICAL IMPURITY(ES)†	
Rosuvastatin Ketone	1A00050
Rosuvastatin Lactone	1A01200

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In addition, USP's Pharmaceutical Analytical Impurity products for Rosuvastatin include the following Impurity:

Rosuvastatin Isoamyl Ester	1A00170
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† Pharmaceutical Analytical Impurities (PAI products) are released using a process developed by USP's subject matter experts. The release process is based on internal policies, standard operating procedures, and requirements as defined by USP's Quality Management System. USP is an ISO 9001:2015 certified facility. PAI products are different from official USP Reference Standards. PAI products are not required for compendial compliance.

08/17/2022. For publications related to **rosuvastatin** in PF online after this date, please visit the Integrated USP-NF/PF online.

[Order Now](#) [Download the USP reference standards app](#) [Ask a Scientist](#)

A **Quality Solution Sheet** is a single resource that integrates newly released RS and monographs with all relevant associated physical materials, PAIs, and eventually General Chapters, excipients, education, and other products and services—*all in one place.*

The Internal QSS Value Proposition



The QSS will help USP...

- ▶ **Change the perception of USP being simply the supplier of RS to being a comprehensive solutions provider**
- ▶ **Deepen the engagement with customers by opening conversations on use of standards across lifecycle**
- ▶ **Integrate monographs and all products and services in one piece of collateral that also**
 - Promotes multiple USP products and services leveraging new or revised RS or monographs
 - Drives usage of USP monographs and General Chapters, and subsequently related products and services
 - Produces more robust analytics on users because we can effectively track usage within USPNF.
 - Create an environment to foster donations of methods
- ▶ **Provide a natural bridge to our solutioning portal “ATLAS” for which a platform is currently underway**
- ▶ **Provide more targeted, responsive and effective customer service and account management.**

The External QSS Value Proposition



The QSS will help our customers...

- ▶ Learn what's NEW at USP and how it could be relevant to their activities
- ▶ Utilize the fast, easy access to all the USP products and services around any one molecule within a few clicks
- ▶ Perceive USP as a comprehensive solutions provider and enable them to optimize USP products and services
- ▶ Leverage USP products and services across lifecycle of research, manufacturing, transport, and storage
- ▶ Begin to understand and transition to our solutioning portal **"ATLAS"** for which a platform is currently underway

Triggers for a Quality Solution Sheet

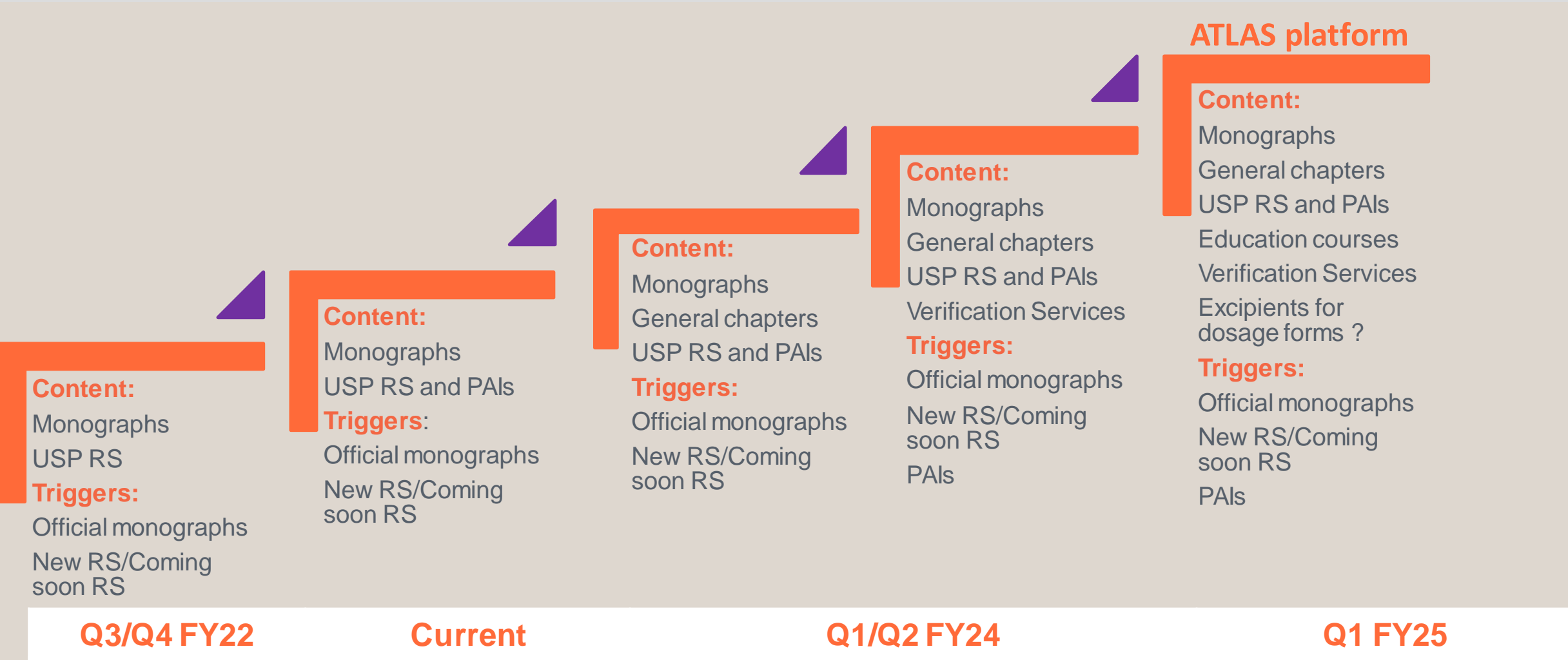


The QSS campaign cycle runs every 4-6 weeks and has current and future instigators:

Current Triggers

- **Trigger 1 – Newly Released (F-lot) or Newly Revised (R-lot) Reference Standards**
 - Denotes monograph status (official, PF)
 - Denotes USP RS and PAI status (new, coming soon)
- **Trigger 2- Newly Official or Recently Revised Monographs**
 - Leverage one monograph to promote multiple associated monographs, physical materials, and services
 - Explain and promote modifications and revisions
- **Future Triggers**
 - **Newly official or modified General Chapter**
 - **New PAIs**
 - **New educational offerings**
 - **New verification services**

Evolution of QSS Campaigns



QSS Digital Marketing Campaigns



Platform



Promotion

Targeted Pardot emails drive traffic to new QSS releases housed on a Pardot landing page

Pardot page/USP.org housing the QSS, *as well as provide home to future assets like a blog, our videos, and other quality solutions collateral.*

Screencast video demo of the QSS navigation from NF/PF to showcase the “new tool” that saves time, mitigates risk and consolidates workflow. On LinkedIn and Facebook

“**Live in the Lab**” series of shorts featuring USP scientists utilizing the QSS and the solutioning approach (and extolling its virtues). On LinkedIn and Facebook

Banner ads on uspnf.com, USP store. CTA to videos, articles, QSS on Pardot page/USP.org page

QSS in the Field: The SCD Toolkit



- ▶ **QSS Toolkit** sent to all SCD and Authorized Distributors (AD) with every QSS deployment
- ▶ **Toolkit contains** SCD Hub links to all new QSS, an SCD Summary Sheet, an AD Summary Sheet, and the email template we used to deploy to target accounts
- ▶ **Feedback and discussion elicited** from SCD and ADs on customer engagement using the QSS
- ▶ **At conferences and events**, hard copies are in the booth and on iPad for demonstration

Promotional Voice, Tag Lines, Messaging



Risk is an expensive substitute for quality compendial standards.

Quality? Essential. Extra Time and Extra Paperwork? Optional.

Develop and convey **the time-saving attributes** of integrating the USP RS, monographs, excipients, PAIs and more.

Don't Lose The News!

Leveraging the headliner effect: that the QSS is a new tool with new advantages to people throughout the lifecycle of manufacturing and to cost and efficiency throughout product development.

Risk—less is more

Less risk, more trust.

Less risk, more confidence.

Less risk, greater reach



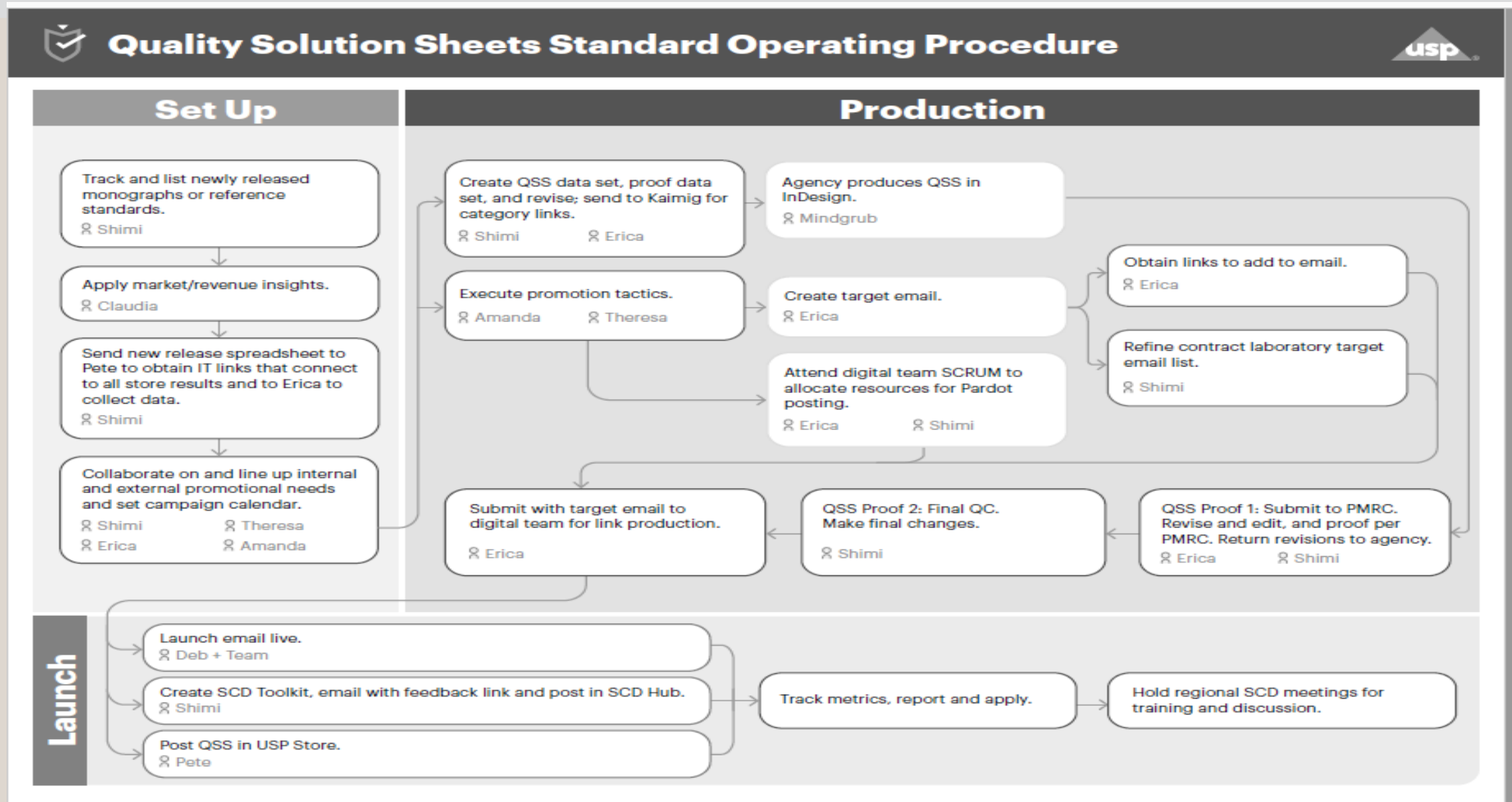
QSS is a holistic tool enabling industry to mitigate risk (add specifics, FDA failure, etc.)

Tactical Marketing Plan



Week	June 2024	July 2024	Aug 2024	Sep 2024	Oct 2024	Nov 2024	Dec 2024
1		Launch 1: QSS deployment & SCD Toolkit 32K+ target accounts email blast	SCD training Authorized Distributors (AD) training	Launch 2: QSS deployment & SCD Toolkit 25K+ target accounts email blast	Pardot page development as QSS repository, with banner, links	Launch 3: QSS deployment and SCD Toolkit	
2		New collateral (QSS) shared with SCD/AD)		New collateral (QSS) Review with SCD/AD)			New collateral (QSS) shared with SCD/AD)
3		SCD Training: Introduction to QSS		AD training on QSS	AAPS, Boston conference: QSS featured in booth (hardcopy and electronically).	EAS, NJ conference: QSS booth promotion	
4						CPHI WW, Frankfurt: QSS booth promotion	
5							
ongoing	Articles/Use Cases for each			Script and Storyboard for QSS screencast video to PMRC Screencast video final edits and PMRC Approval			

Automating the QSS: Setup, Production, and Launch



Stay Connected

Phone | Social Media | Email



The standard of trust