



EXPERTISE

SAFETY

SOLUTIONS

CDISC Library try-out: from implementation to evaluation of the API

Roman Radelicki – Team Manager Data Programming, SGS

PHUSE US Connect 2020 - Orlando | 8-11 March 2020

WHEN YOU NEED TO BE SURE

SGS



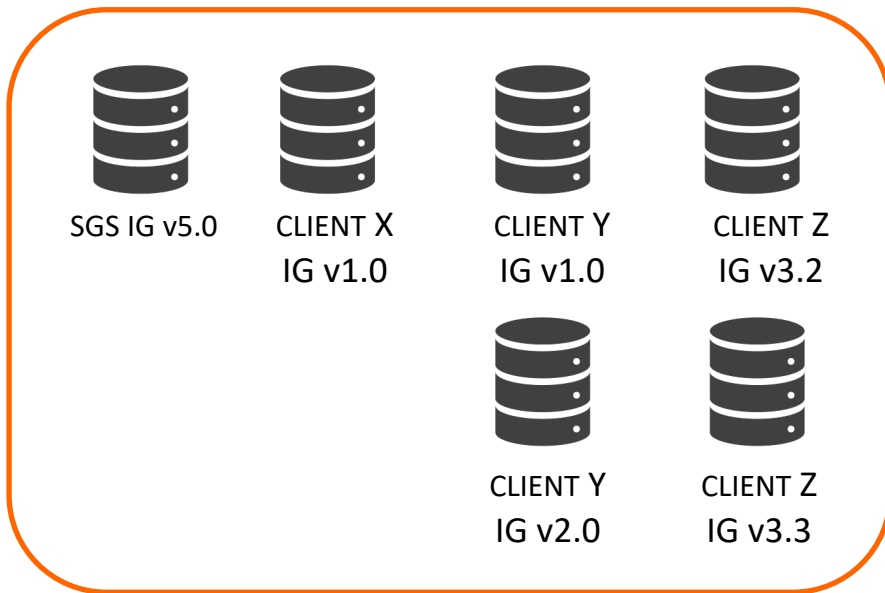
- Metadata Centric Approach
- CDISC 360 – CDISC Library
- Trial Summary
- CDISC Library - API calls
- Conclusion

Metadata Centric Approach

Our current way of working



METADATA CENTRIC APPROACH



Trials

Client A – Trial A



SGS IG v5.0

Client B – Trial B



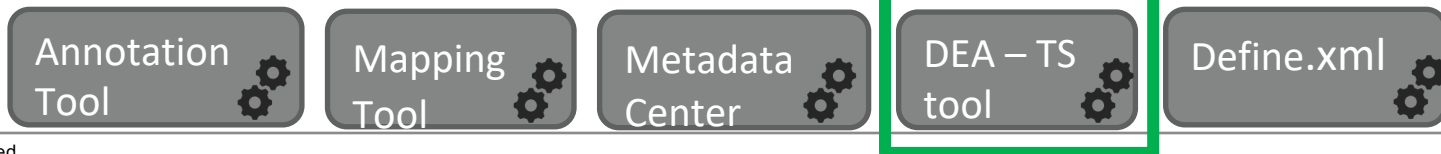
SGS IG v5.0

Client Y – Trial Y



CLIENT Y IG v2.0

MDR Driven Tools



CDISC 360 – CDISC Library



- Biomedical concepts: create meaning between data
- Standards as linked metadata
- metadata-driven end-to-end automation
- Non-standard experts use the CDISC standards
- CDISC Library REST API



API?

- Application programming interface
- Key building blocks in service digitalization and integration
- The restaurant analogy
 - As a customer → not allowed in the kitchen
 - To know what's available → menu
 - Make your order to a waiter
 - The waiter passes it to the kitchen and will deliver what you have asked for
 - Waiter = API
 - Menu = documentation
 - Kitchen = server/database



Trial Summary Case study





■ TS

- Part of the Trial Design datasets
- describe the characteristics of the trial
- such as trial phase, protocol title, and trial objectives

■ In house developed tool to create the TS dataset

- Created manually
- Values controlled by terminology

■ Ideal case study candidate

- Try out CDISC Library API
- Linked metadata

HOME

STAGES (LIVE)

MODULES

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another

Copy template to trial

Import

View ALL audit data



Search: All Text Columns

Go

Actions

Edit

Save

Add TS record

Reset



TSPARMCD ↑≡1

TSPARM

TSVAL

TSVALCD

TSVCDREF

TSVCDVER



No TS data present !

HOME

STAGES (LIVE)

MODULES

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another

Copy template to trial

Import

View ALL audit data



Search: All Text Columns

Go

Actions

Edit

Save

Add TS record

Reset



TSPARMCD ↑≡1

TSPARM

TSVAL

TSVALCD

TSVCDREF

TSVCDVER



1 rows selected

Total 1

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
TSPARMCD	Trial Summary Parameter Short Name	Char	TSPARMCD	Topic	TSPARMCD (the companion to TSPARM) is limited to 8 characters and does not have special character restrictions. These values should be short for ease of use in programming, but it is not expected that TSPARMCD will need to serve as variable names. Examples: AGEMIN, AGEMAX	Req

Code	Codelist Code	Codelist Extensible (Yes/No)	CDISC Submission Value	CDISC Synonym(s)
C66738		Yes	TSPARMCD	Trial Summary Parameter Test Code
C98703	C66738		ACTSUB	Actual Number of Subjects
C146995	C66738		ADAPT	Adaptive Design
C49703	C66738		ADDON	Added on to Existing Treatments
C49694	C66738		AGEMAX	Planned Maximum Age of Subjects
C49693	C66738		AGEMIN	Planned Minimum Age of Subjects

HOME

STAGES (LIVE)

MODULES

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another

Copy template to trial

Import

View ALL audit data



Search: All Text Columns

Go

Actions

Edit

Save

Add TS record

Reset



TSPARMCD ↑≡1

TSPARM

TSVAL

TSVCD

TSVCDREF

TSVCDVER



1 rows selected

Total 1

[HOME](#)
[STAGES \(LIVE\)](#)
[MODULES](#)
[TS](#)
[Templates](#)

TRIAL SUM

Search Dialog - TSPARMCD






☒ TSPARMCD ↑


1 rows

ACTSUB - Actual Number of Subjects

ADAPT - Adaptive Design

ADDON - Added on to Existing Treatments

AGEMAX - Planned Maximum Age of Subjects

AGEMIN - Planned Minimum Age of Subjects

BIOSPRET - Biospecimen Retention Contains DNA

Y-TRIAL

TSVALCD

TSVCDREF

TSVCDVER

Total 1

HOME

STAGES (LIVE) ▼

MODULES ▼

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another

Copy template to trial

Import

View ALL audit data



Search: All Text Columns

Go

Actions ▼

Edit

Save

Add TS record

Reset



TSPARMCD ↑≡1

TSPARM

TSVAL

TSVALCD

TSVCDREF

TSVCDVER



ADAPT

Adaptive Design

1 rows selected

Total 1



HOME

STAGES (LIVE) ▾

MODULES ▾

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another

Copy template to trial

Import

View ALL audit data



Search: All Text Columns

Go

Actions ▾

Edit

Save

Add TS record

Reset



TSPARMCD ↑≡1

TSPARM

TSVAL

TSVALCD

TSVCDREF

TSVCDVER



ADAPT

Adaptive Design

|

1 rows selected

Total 1

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
TSVAL	Parameter Value	Char	*	Result Qualifier	Value of TSPARM. Example: "ASTHMA" when TSPARM value is "Trial Indication". TSVAL can only be null when TSVALNF is populated. Text over 200 characters can be added to additional columns	Exp

TS – Examples for Trial Summary Information Dataset

Example 1:

This example shows all of the parameters that are required or expected in the Trial Summary dataset.

Use controlled terminology for TSVAL (see [NCI EVS Terminology Resources](#)).

Row	STUDYID	DOMAIN	TSSEQ	TSGRPID	TSPARMCD	TSPARM	TSVAL	TSVALNF	TSVALCD	TSVCDREF	TSVCDVER
1	XYZ	TS	1		ADDON	Added on to Existing Treatments	Y		C49488	CDISC	2011-06-10
2	XYZ	TS	1		AGEMAX	Planned Maximum Age of Subjects	P70Y			ISO 8601	
3	XYZ	TS	1		AGEMIN	Planned Minimum Age of Subjects	P18M			ISO 8601	
4	XYZ	TS	1		LENGTH	Planned Trial Length	P3M			ISO 8601	
5	XYZ	TS	1		PLANSUB	Planned Number of Subjects	300				
6	XYZ	TS	1		RANDOM	Trial is Randomized	Y		C49488	CDISC	2011-06-10

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
TSVAL	Parameter Value	Char	*	Result Qualifier	Value of TSPARM. Example: "ASTHMA" when TSPARM value is "Trial Indication". TSVAL can only be null when TSVALNF is populated. Text over 200 characters can be added to additional columns	Exp

Appendix C1: Trial Summary Codes

The Parameter table includes text to indicate if the parameter should be included in the dataset.

To make this domain useful, a minimum number of trial summary parameters should be provided as shown below. The column titled "Record with this Parameter" indicates whether the parameter should be included in the dataset. If a record is included, either TSVAL or TSVALNF must be populated.

Most of the new parameters are coming from www.clinicaltrials.gov and the controlled terminology shown below is aligned with that source. All definitions of the parameters are maintained in NCI EVS.

The Notes column provides some additional information about the specific parameter or its values.

TSPARMCD	TSPARM	TSVAL (Codelist Name or Format)	Record with this Parameter	Notes
ADDON	Added on to Existing Treatments	No Yes Response	Required	
AGEMAX	Planned Maximum Age of Subjects	ISO 8601	Required	If there is no maximum age, TSVALNF = PINF
AGEMIN	Planned Minimum Age of Subjects	ISO 8601	Required	If there is no minimum age, populate TSVAL with P0Y
LENGTH	Planned Trial Length	ISO 8601	Required	
PLANSUB	Planned Number of Subjects	number	Required	
RANDOM	Trial is Randomized	No Yes Response	Required	

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
TSVAL						Exp

Contains Nonbinding Recommendations



Appendix B: Trial Summary (TS) Parameters for Submission – Clinical

* Indica

Copy TS da

FDA Desired - Clinical	TSPARMCD	TSPARM	FDA Notes
Y	ACTSUB	Actual Number of Subjects	
Y	ADAPT	Adaptive Design	
Y	ADDON	Added on to Existing Treatments	
Y	AGEMAX	Planned Maximum Age of Subjects	
Y	AGEMIN	Planned Minimum Age of Subjects	
Y	COMPTRT	Comparative Treatment Name	
Conditional	CRMDUR	Confirmed Response Minimum Duration	If applicable.
Conditional	CTAUG	CDISC Therapeutic Area User Guide	If applicable, the value should be the exact listing as in section 5.2 of the Technical Conformance Guide.

de value)

ALL audit data

Reset

TSVCDVER

Total 1

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
TSVAL	Parameter Value	Char	*	Result Qualifier	Value of TSPARM. Example: "ASTHMA" when TSPARM value is "Trial Indication". TSVAL can	Exp

+ Codetable Mapping Files

Controlled Terminology consists of question (e.g., Variables, TESTs and PARMs) and answer(e.g., response

SDTMIG3.2 Variable_Codelist

C-code (Concept Code)	Trial Summary Parameter Test Code (TSPARMCD) (codelist code = C66738)	Trial Summary Parameter Test Name (TSPARM) (codelist code = C67152)	C-code (Concept Code)	No Yes Response (NY) (codelist code = C66742)
C98703	ACTSUB	Actual Number of Subjects		
C146995	ADAPT	Adaptive Design	C49487	N
C146995	ADAPT	Adaptive Design	C17998	U
C146995	ADAPT	Adaptive Design	C49488	Y

constitutes a subset of the EGSTRESC codelist. Another instance, a single VSTEST value may have a constrained set of units of measure that are valid for the numeric responses to that VSTEST. These relationships are not readily apparent in the Controlled Terminology publication files.

TS Codetable

VS Codetable

HOME

STAGES (LIVE) ▼

MODULES ▼

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another

Copy template to trial

Import

View ALL audit data



Search: All Text Columns

Go

Actions ▼

Edit

Save

Add TS record

Reset



TSPARMCD ↑≡1

TSPARM

TSVAL

TSVALCD

TSVCDREF

TSVCDVER



ADAPT

Adaptive Design

|

1 rows selected

Total 1



HOME

STAGES (LIVE)

MODULES

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another



Search: All Text Columns

Go

Actions

Edit



TSPARMCD ↑≡1

TSPARM

TS



ADAPT

Adaptive Design

1 rows selected

Search Dialog - TSVAL



Search

N - C49487

U - C17998

Y - C49488

View ALL audit data

Reset

TSVCDVER

Total 1

HOME

STAGES (LIVE)

MODULES

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another

Copy template to trial

Import

View ALL audit data



Search: All Text Columns

Go

Actions

Edit

Save

Add TS record

Reset



TSPARMCD ↑≡1

TSPARM

TSVAL

TSVALCD

TSVCDREF

TSVCDVER



ADAPT

Adaptive Design

Y

C49488

CDISC

2019-06-28

1 rows selected

Total 1

CDISC LIBRARY API calls



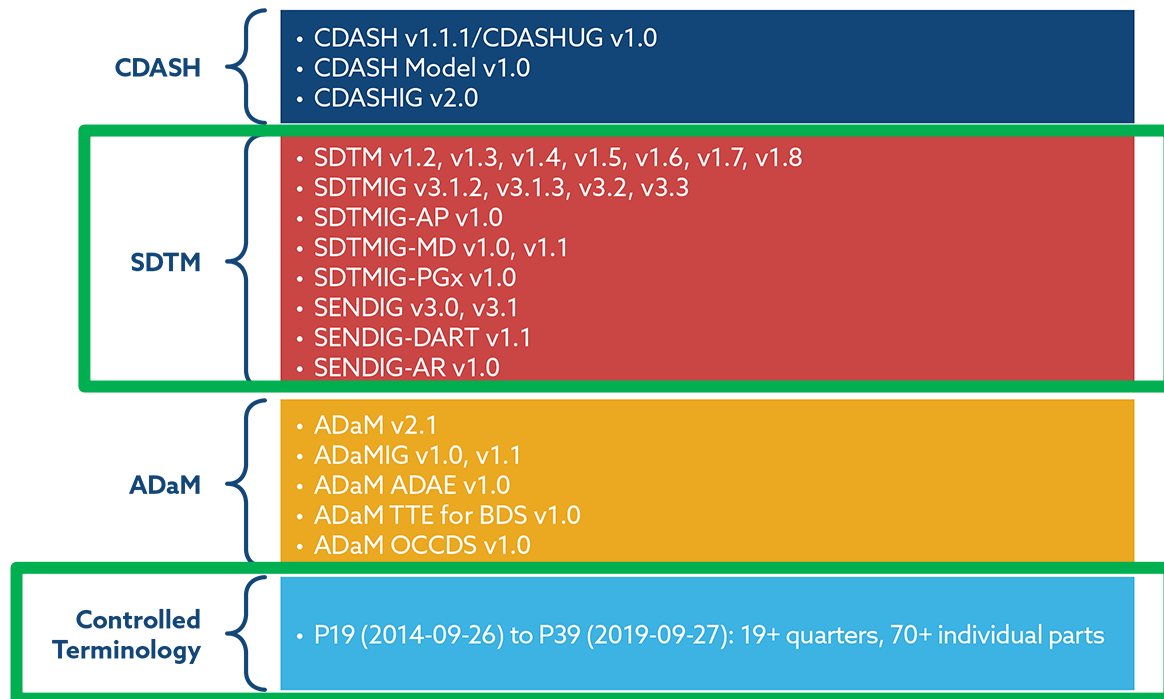
Can we use API requests in stead of our MDR?



- Are the standards we need available in CDISC Library?
- How do I create an CDISC Library Account?
- Can we retrieve the information needed for the TS tool?
- Is more linked metadata available?

Can we use API requests in stead of our MDR?

- Are the standards we need available in CDISC Library?





CDISC LIBRARY - API CALLS

**Can we use API requests in
stead of our MDR?**

- How do I create an
CDISC Library Account?



- <https://www.cdisc.org/cdisc-library>
- Request an account
- CDISC Library API Account Request
- License Agreement
- Welcome package: information to get you started
- Account details to access the CDISC Library API

Can we use API requests in stead of our MDR?

- Can we retrieve the information needed for the TS tool?

HOME

STAGES (LIVE)

MODULES

TS

Templates

TRIAL SUMMARY

TRIAL: SGS-DUMMY-TRIAL

Copy TS data from one stage to another

Copy template to trial

Import

View ALL audit data



Search: All Text Columns

Go

Actions

Edit

Save

Add TS record

Reset



TSPARMCD ↑≡1

TSPARM

TSVAL

TSVCD

TSVCDREF

TSVCDVER



1 rows selected

Total 1

HOME

STAGES (LIVE)

MODULES

TS

Templates

TRIAL SUM

Search Dialog - TSPARMCD



Search

ACTSUB - Actual Number of Subjects

ADAPT - Adaptive Design

ADDON - Added on to Existing Treatments

AGEMAX - Planned Maximum Age of Subjects

AGEMIN - Planned Minimum Age of Subjects

BIOSPRET - Biospecimen Retention Contains DNA



Search: All T



TSPARMCD ↑↓



1 rows selected



Y-TRIAL

Copy template to trial

Import

View ALL audit data

Add TS record

Reset

TSVALCD

TSVCDREF

TSVCDVER

Total 1

Create API request to get more info about the TSPARMCD from the SDTM Implementation Guide

- From the CDISC Library documentation:

GET /mdr/sdtmig/{version}/datasets/{dataset}/variables/{var} Get SDTMIG Dataset Variable

- API Call:

  <https://library.cdisc.org/api/mdr/sdtmig/3-2/datasets/TS/variables/TSPARMCD>

XML?

- Extensible Markup Language
- format for representing data that is both human-readable and machine-readable

```
- <library>  
  - <books>  
    <book name="XML for dummies"/>  
    <book name="API's for dummies"/>  
  </books>  
</library>
```



XML result:

```
- <datasetVariable>
  <ordinal>5</ordinal>
  <name>TSPARMCD</name>
  <label>Trial Summary Parameter Short Name</label>
+ <description></description>
  <role>Topic</role>
  <simpleDatatype>Char</simpleDatatype>
  <core>Req</core>
- <_links>
  + <self></self>
  - <codelist>
    <href>/mdr/root/ct/sdtmct/codlists/C66738</href>
  - <title>
    Version-agnostic anchor resource for codelist C66738
  </title>
  <type>Root Value Domain</type>
</codelist>
```

Next API call: TSPARMCD codelist:

</mdr/root/ct/sdtmct/codelists/C66738>

■ From the CDISC Library documentation:

GET

/mdr/ct/packages/{package}/codelists/{codelist}/terms Get CT Package Codelist Term List

■ API Call:

  <https://library.cdisc.org/api/mdr/ct/packages/sdtmct-2019-06-28/codelists/C66738/terms>

XML result:

```
- <cdiscLibrary>
  - <codelist>
    <conceptId>C66738</conceptId>
    <extensible>true</extensible>
    <name>Trial Summary Parameter Test Code</name>
    <submissionValue>TSPARMCD</submissionValue>
    - <term>
      - <href>
        /mdr/ct/packages/sdtmct-2019-06-28/codelists/C66738/terms/C98703
      </href>
      <title>Actual Subject Number</title>
      <type>Code List Value</type>
    </term>
    - <term>
      - <href>
        /mdr/ct/packages/sdtmct-2019-06-28/codelists/C66738/terms/C146995
      </href>
      <title>Adaptive Study Design Indicator</title>
      <type>Code List Value</type>
    </term>
```

Next API call: term “adaptive Study Design Indicator”:

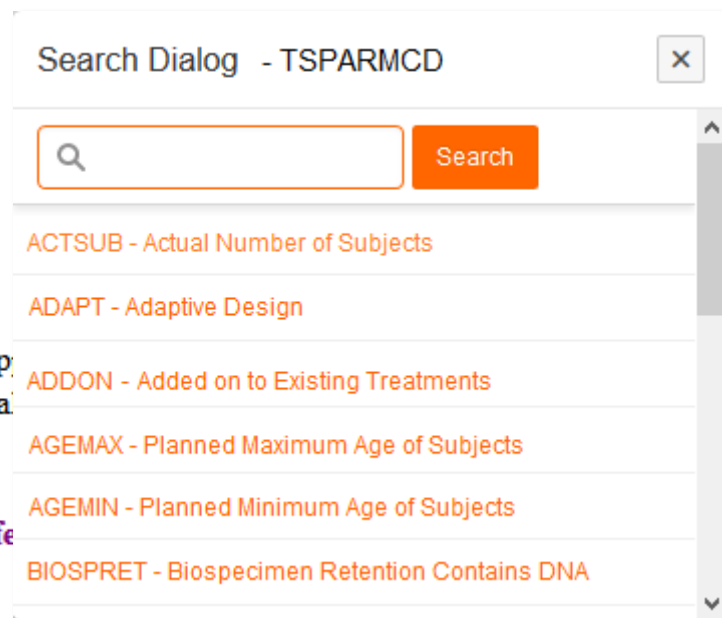
[/mdr/ct/packages/sdtmct-2019-06-28/codelists/C66738/terms/C146995](https://library.cdisc.org/api/mdr/ct/packages/sdtmct-2019-06-28/codelists/C66738/terms/C146995)

■ API Call:

  <https://library.cdisc.org/api/mdr/ct/packages/sdtmct-2019-06-28/codelists/C66738/terms/C146995>

XML result:

```
-<cdiscLibrary>
-  <term>
    <conceptId>C146995</conceptId>
    <submissionValue>ADAPT</submissionValue>
    <definition>
      Indicate if the study includes a prospectively planned op
      aspects of the study design and hypotheses based on ana
      study.
    </definition>
    <preferredTerm>Adaptive Study Design Indicator</prefe
    <synonyms>Adaptive Design</synonyms>
    + <_links></_links>
  </term>
</cdiscLibrary>
```



Can we use API requests in stead of our MDR?

- Can we retrieve the information needed for the TS tool?



**Can we use API requests in
stead of our MDR?**

- Is more linked metadata
available?



- TSVAL variable: may be subject to
controlled terminology
- Additional information from the PDF
version of the SDTMIG
- Codetable mapping files from the CDISC
website
- FDA SDTCG TS parameters list

This case study only touches a fraction of the CDISC 360 concept and its focus is on this level of SDTM and Controlled Terminology for the TS domain

- By only making use of the CDISC Library API in our TS tool, we can't provide same functionalities
- Codetable mapping file implementation still needed in the TS tool
- CDISC SHARE vs CDISC Library API
 - Versioning traceability
 - Additional linked metadata missing
- CDISC Library API vs in-house MDR
 - Availability, dependency
 - API: most recent information
- I believe CDISC has laid the foundations
 - Automatized standards-based processes
 - The more linked metadata becomes available, the better software it will deliver



ADVANCED **CLINICAL** **RESEARCH** SOLUTIONS

LIFE INSPIRED, QUALITY DRIVEN

CONTACT US



clinicalresearch@sgs.com



EUROPE: +32 15 27 32 45
AMERICAS: +1 877 677 2667



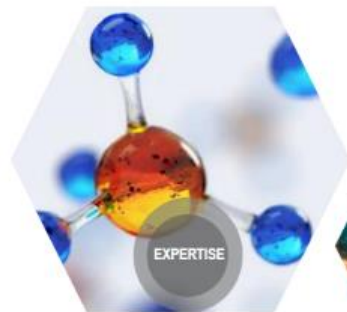
www.sgs.com/cro

JOIN US at the **SGS BOOTH 31**



JOIN THE SCIENTIFIC COMMUNITY

Discover R&D market news and events
www.sgs.com/LinkedIn-Life



WWW.SGS.COM

WHEN YOU NEED TO BE SURE

SGS