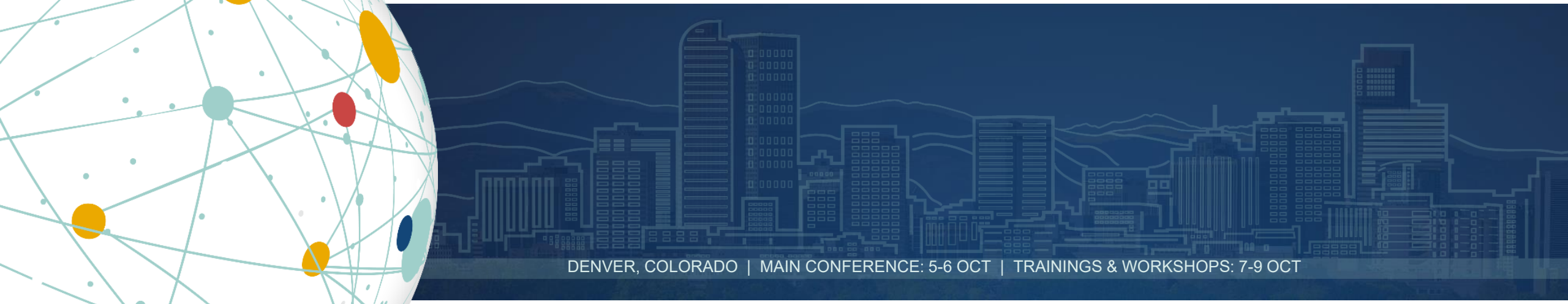


2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



From Intent to Execution: How Biomedical Concepts Quietly Rewired the Safety Data Pipeline

Chithra Subramaniam, Associate Director, Bristol Myers Squibb, NJ
Rohini Goyal, Senior Manager, Bristol Myers Squibb, NJ

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Speakers

Chithra Subramaniam is an Associate Director of Clinical Data Standards at **Bristol Myers Squibb**, where she leads enterprise-wide initiatives at the intersection of protocol standardization, digitization, and clinical trial data collection standards.

In her role, Chithra drives the governance and harmonization of critical protocol standards — spanning **endpoints, study activities, and biomedical concepts and CRFs** — ensuring consistency, quality, and efficiency across BMS's global clinical programs. She works closely with cross-functional stakeholders to align data collection practices and unlock the reuse of clinical data assets across therapeutic areas, enabling smarter and more streamlined trial execution.

A recognized voice in the field, Chithra champions the advancement of **protocol and data standards** — bridging the gap between protocol intent and downstream data quality in direct support of BMS's mission to deliver transformative medicines to patients.

Chithra Subramaniam

Associate Director

Bristol Myers Squibb



Speakers

Rohini Goyal is a Senior Manager of Clinical Data Standards at **Bristol Myers Squibb**, with extensive experience in clinical study data, eCRFs, database implementation, and data standardization. Her work spans protocol digitization, biomedical concepts, CRF and non-CRF standards, SDTM mapping, controlled terminology, metadata governance and Biomarker Data Standardization. She collaborates across functions to connect protocol intent with consistent, reusable, and high-quality clinical data standards

In her current role, Rohini specializes in operationalizing CDISC USDM through protocol digitization, biomedical concepts, metadata governance, Metadata integration, Schedule of Activities standardization, enterprise terminology management, and end-to-end Digital Data Flow implementation. Leading enterprise initiatives focused on the standardization and governance of Non-CRF clinical data, enabling harmonized collection, integration, and submission of biomarker, laboratory, imaging, vendor, and other external data sources.

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Rohini Goyal

Sr. Manager

Bristol Myers Squibb



Agenda

1. From Intent to Execution
2. Objectives for the Session
3. Recognize Semantic Drift
4. The Hidden Cost
5. The Reframe – Enterprise Safety Assets
6. What are Biomedical Concepts
7. The Semantic Contract
8. Validation by Design
9. BC Maturity Level
10. The Cultural Challenge
11. Change Management Playbook
12. Safety Objective to SDTM Traceability
13. Pipeline is being Rewired

FROM INTENT TO EXECUTION

What and how Biomedical Concepts Quietly Rewired the Safety Data Pipeline

Think of it as clinical data's version of telephone:

STAGE	Protocol	CRF	SDTM	ADaM	Submission
HANDLER	Protocol Authors	CRF Designers	Programmers	Statisticians	Medical Writers
THEIR LENS	Science	Usability	Conformance	Analysis	Narrative

One scientific intent, interpreted through five different operational lenses.

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OBJECTIVES FOR THE SESSION

By the end of this session, you will be able to:

1. ☑ Explain what semantic drift is and where it occurs
2. ☑ Describe what CDISC Biomedical Concepts are
3. ☑ Understand what enterprise safety assets means
4. ☑ Explain the 3 levels of BC maturity
5. ☑ Describe validation by design in practice
6. ☑ Articulate the cultural challenges and how to address them

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RECOGNIZE SEMANTIC DRIFT

The semantic drift is the gradual, invisible distortion of meaning as safety intent passes through each pipeline stage – not because anyone intends it, but because human interpretation under timeline pressure is the only thing connecting the layers. Each team optimizes for a legitimate objective, but the end-to-end meaning has no persistent owner.

Five Stages. Five Valid Lenses. Four Vulnerable Handoffs.



Real Examples of Drift

- **Protocol says Day 1/15/29 → SDTM maps Day 1/14/28 *(timing mismatch)***
- **Protocol implies 5-point severity → CRF captures 3-point *(scale drift)***
- **ADaM flag uses different onset date than protocol intended *(context drift)* ; Programmer uses RANDDT (randomization date) instead of TRTSTDTC (after the first dose of study drug)**

Meaning must be carried forward as an explicit, traceable semantic contract.

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THE HIDDEN COST

The same safety questions – reinvented on every study:
Did the patient have an AE? When? How severe? Was it treatment-related?

Every study pays the reinterpretation tax

Time
Reconciliation meeting; late-stage query resolution

Quality
Inconsistent severity scales across studies

HIDDEN TAX
(paid across every study)

Compliance
Audit findings on variable derivations

Regulatory
Submission queries tracing endpoints to source data

Expertise
Reinterpretation, Not Science

Because the cost is distributed across teams, studies, and timelines , it rarely appears on any single project's risk register – yet it is paid , repeatedly, on every study.

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THE REFRAME – Enterprise Safety Assets

Treat safety endpoints as enterprise assets

Move from local reinvention to governed reuse.

OLD QUESTION

- How do we build CRFs faster?
- How do we program SDTM more efficiently?
- How do we reduce reconciliation time?

→

NEW QUESTION

What if safety endpoints were enterprise assets — defined once, governed centrally, reused everywhere with meaning intact?

What makes something an Enterprise Asset?

- **Defined once** — not duplicated locally per study
- **Governed centrally** — owned, versioned, maintained
- **Reused broadly** — across studies, programs, therapeutic areas
- **Stable meaning** — definition does not change by who uses it

The key shift: Reference the enterprise definition instead of copying and reinterpreting it.

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WHAT ARE BIOMEDICAL CONCEPTS

Machine-readable meaning

A Biomedical Concept (BC) is a structured, machine-readable representation of a clinical measurement that captures what is measured, how, in what context, and with what vocabulary.

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Anatomy of a BC: BC_AE • Solicited Adverse Event

DOMAIN	AE
DATA ELEMENT CONCEPT	Reported Adverse Event
VALUES	Headache , Rash
TIMING	First dose → last dose + 30 days
DATA ELEMENT CONCEPT	Severity of Adverse Event
VALUES	Y / N
TIMING	First dose → last dose + 30 days
GOVERNANCE	Enterprise Safety Standards Library

KEY INSIGHT

A BC is not just a label. It is a **definition that carries its own instructions** — and when linked to an enterprise safety endpoint, it becomes a **semantic contract**: a promise that this data element means the same thing wherever it appears.

What BCs Are NOT:

- ✗ Just another data dictionary
- ✗ A study-specific CRF annotation
- ✗ A documentation artifact that lives in a folder

What BCs ARE:

- ✓ Machine-readable meaning
- ✓ A passport for safety intent
- ✓ The connective tissue of Digital Data Flow

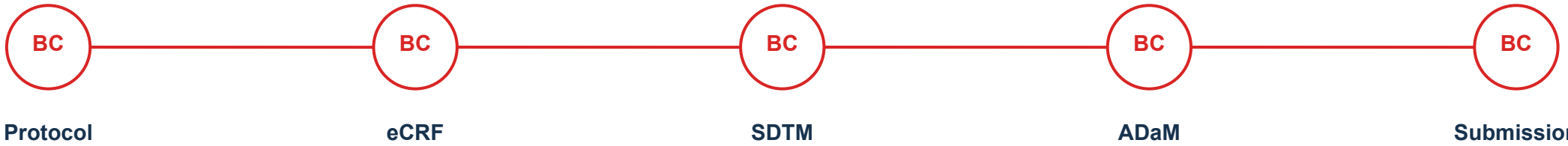
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THE SEMANTIC CONTRACT

One identifier. One meaning. Every artifact.

The same BC identifier appears at every level. Pull that thread at any point — study build, data collection, analysis, submission — and the system can verify: *does this artifact's meaning align with its intended endpoint?*



Proof Point 1 - BC-DRIVEN eCRF DESIGN



- ✓ Field meaning consistent across studies
- ✓ Controlled terminology inherited
- ✓ Timing context from the standard study activity

“"Safety eCRFs that looked familiar to sites, yet were semantically consistent by design”

Proof Point 2 - SEMANTIC VALIDATION BEFORE FIRST PATIENT



BC identifiers embedded across artifacts

- ✓ Automated cross-artifact checks during study build
- ✓ Timing mismatches, and context drift caught early
- ✓ Terminology conflicts identified before execution

“This wasn't just earlier QC. It was validation by design.”

Meaning is verified, not re-inferred.

SAFETY OBJECTIVE TO SDTM TRACEABILITY

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Objective → Endpoint → Activity → BC Group → Biomedical Concept → CRF → SDTM

SAFETY OBJECTIVE
Evaluate the safety and tolerability of a single 0.4 mg oral dose of paracetamol in participants with moderate and severe Headache

SAFETY ENDPOINT
Incidence, severity, investigator causality assessment, and all AEs and SAEs

ACTIVITY
Adverse Events

BC GROUP
Events; Reported Events; Adverse Events

BC MAPPING –SHORT NAME
BC ID: C179175
Solicited Adverse Event

Additional safety activities: Vital Signs, ECG etc.

BIOMEDICAL CONCEPT → CRF FIELD → SDTM MAPPING

BC definition: An adverse event reported through an organized data collection system.

CRF FIELD OID	BC DEC ID	BC DEC LABEL	CRF DATA TYPE	CRF PRETEXT	SDTM TARGET	SDTM ANNOTATION
AETERM	C78541	Adverse Event Verbatim Description	string	What is the adverse event term?	AETERM	AETERM
AESTDAT	C83215	Adverse Event Start Date Time	datetime	What is the adverse event start date?	AESTDAT	AESTDAT
AESEV	C53253	Severity of Adverse Event	string	What is the severity of the adverse event?	AESEV	AESEV

TRACEABILITY THREAD Safety intent is connected to collection meaning through DEC identifiers and carried into the AE SDTM variables.

SOURCE: OE_Activity_BC_SDTM.xlsx

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VALIDATION BY DESIGN

The Fundamental Shift

	Traditional	Validation by Design
When issues found	Database lock / submission	Study build
Who finds them	Humans in meetings	Automated semantic checks
Cost to fix	High → Very High	Low
Traceability	Implicit, fragile	Explicit, machine-readable
Consistency	Manual vigilance	Design precondition

Types of Issues Caught Early:

- **Timing mismatch between protocol and SDTM**
- **CRF captures 3-point scale; SDTM expects 5-point CDISC CT**
- **ADaM derivation assumes definition not encoded in CRF**
- **SDTM variable has no BC identifier — intent unverifiable**

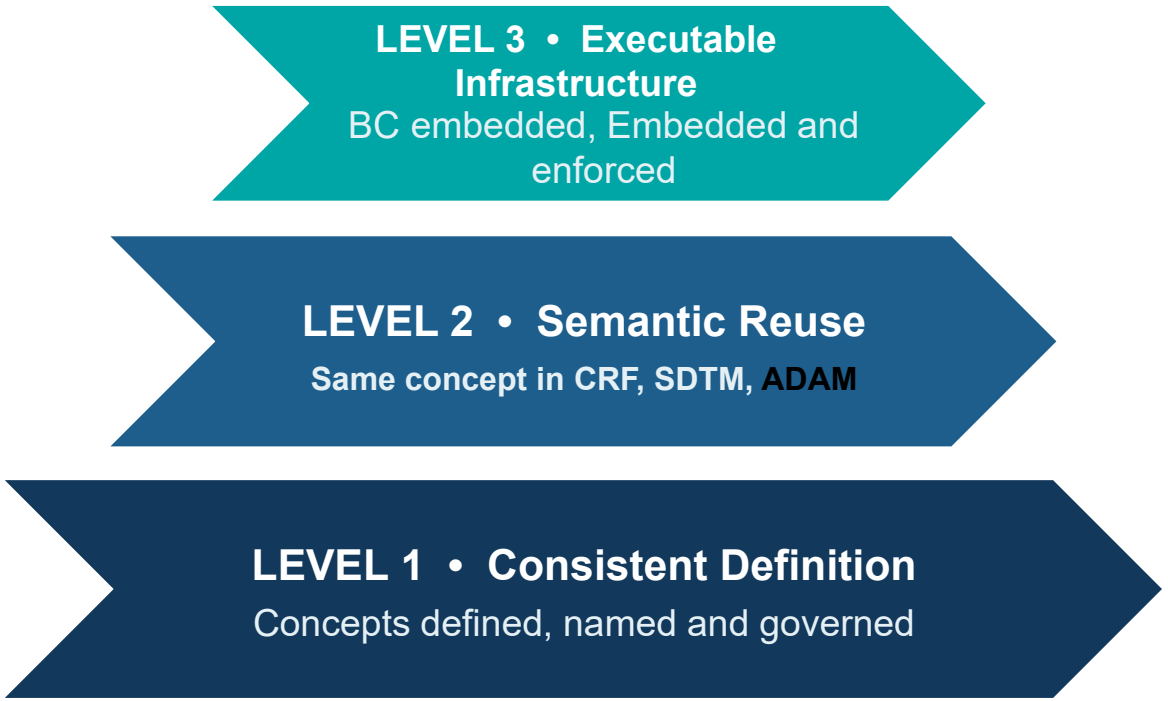
The Key Principle

Validation by design is not about checking more — it is about checking earlier, automatically, and systematically, by building quality into the structure of the artifacts themselves.

BC MATURITY LEVEL

Define → Reuse → Execute

The foundation must exist before automation can deliver value.



LEVELS 1–2

BC in documentation: Describe what should happen

LEVEL 3

BC as infrastructure: Makes it happen

Level 1 is unglamorous. Value is invisible on any single study. But without it, Levels 2 and 3 are impossible. The foundation must be laid before the transformation can happen.

The CULTURAL CHALLENGE

"Ironically, the most challenging part of the journey wasn't technical. It was cultural."

Why Culture Is Harder Than Technology

Technical Challenge:

Define problem → Build solution → Deploy → Done ☑

Cultural Challenge:

1. Define problem → Convince people → Overcome resistance
2. Build habits → Sustain behavior → Handle regression
3. Never fully done 🔄

The Five Barriers

Barrier	Root Cause
Identity & Ownership	Professional identity tied to artifact ownership
Loss of Control	Local control has historically been the QA mechanism
Misaligned Incentives	Study teams measured on study outcomes; standards deliver portfolio benefits
Invisible Progress	You can demo a BC. You cannot measure a mindset shift.
Scar Tissue	Previous standardization initiatives failed. Rational skepticism learned.

What Changed the Dynamic ***"What helped was storytelling — not about efficiency, but about safety itself."***

When teams saw that this approach reduced ambiguity, improved traceability, and created a more durable safety narrative — resistance softened. Automation stopped feeling like loss of control and began to feel like reliability.

CHANGE MANAGEMENT PLAYBOOK

Seven Strategies for Driving Adoption

Practical actions that make the safer path easier, more visible, and more credible.

01 **LEAD WITH SAFETY**
Safety arguments build alignment; efficiency arguments trigger fear.

02 **MAKE EARLY ADOPTERS HEROES**
Let peers tell the success story. It lands differently than leadership mandates.

03 **DESIGN WITH TEAMS, NOT FOR THEM**
Co-design creates advocates, not just compliers.

04 **REDUCE COST OF COMPLIANCE**
Make the right path the easy path.

05 **GOVERNANCE THAT ENABLES**
Guide before the fact, not audit after.

06 **MAKE VALUE VISIBLE**
Track before/after metrics; publicize wins across the organization.

07 **THINK IN HORIZONS**
Phase 3 first → Phase 2 → all studies → retrospective harmonization.

THE GOAL

Redirect ownership

FROM

"I own my CRF"

TO

I"own the quality of my study's safety data"

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THE PIPELINE IS BEING REWIRED

Meaning now travels with the data

A deliberate shift from downstream reconciliation to upstream definition.

01

WHAT CHANGED

Interpretation moved upstream — from downstream reconciliation to upstream definition.

02

WHAT DIDN'T CHANGE

Human judgment remains essential — especially for novel safety signals.

03

THE PATTERN IS REPEATABLE

SAFETY | EFFICACY | BIOMARKERS | PATIENT-REPORTED OUTCOMES | PHARMACOKINETICS | DIGITAL DATA FLOW

A repeatable path from one domain to an integrated digital data flow.

THE CLOSING THOUGHT

"There is something fitting about the fact that this transformation began not with a new technology, but with a question:"

"What if meaning could travel?"

"The pipeline is being rewired. Quietly, deliberately, one concept at a time."

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BC Maturity Self-Assessment Sample Checklist

Capability	☐ Not Started	☐ In Progress	☐ Achieved
Safety concepts consistently defined and named			
Enterprise safety endpoint library exists			
Governance structure in place			
BCs reused across CRF and SDTM			
BC identifiers embedded in SDTM specs			
Automated cross-artifact semantic validation			
Pre-enrollment validation by design active			

GLOSSARY

Term	Plain-English Definition
Semantic Drift	Meaning quietly changing at each pipeline handoff
Biomedical Concept (BC)	A machine-readable, structured definition of what is being measured, how, and in what context
Semantic Contract	The BC's promise that a data element means the same thing everywhere it appears
Enterprise Asset	Defined once, governed centrally, reused everywhere
Validation by Design	Catching misalignments during study build, not database lock
Digital Data Flow	The vision of meaning traveling intact from protocol to submission
USDM	CDISC's Unified Study Definitions Model — machine-readable protocol standard

Thank You!



Questions?

