

Session 7.1

Driving Cost Reduction for C&Q Capital Projects with Digital Validation

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Driving Cost Reduction for C&Q in Capital Projects with Digital Validation

Patrick Mullin

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Presentation Topics

Act 1: Capital Context

Act 2: Core Problem in CQV

Act 3: Interpretation and Translation

Act 4: Measurement

Act 5: Digital CQV

Act 6: Structured Data

Act 7: Future Trajectory

Act 8: Capital Impact

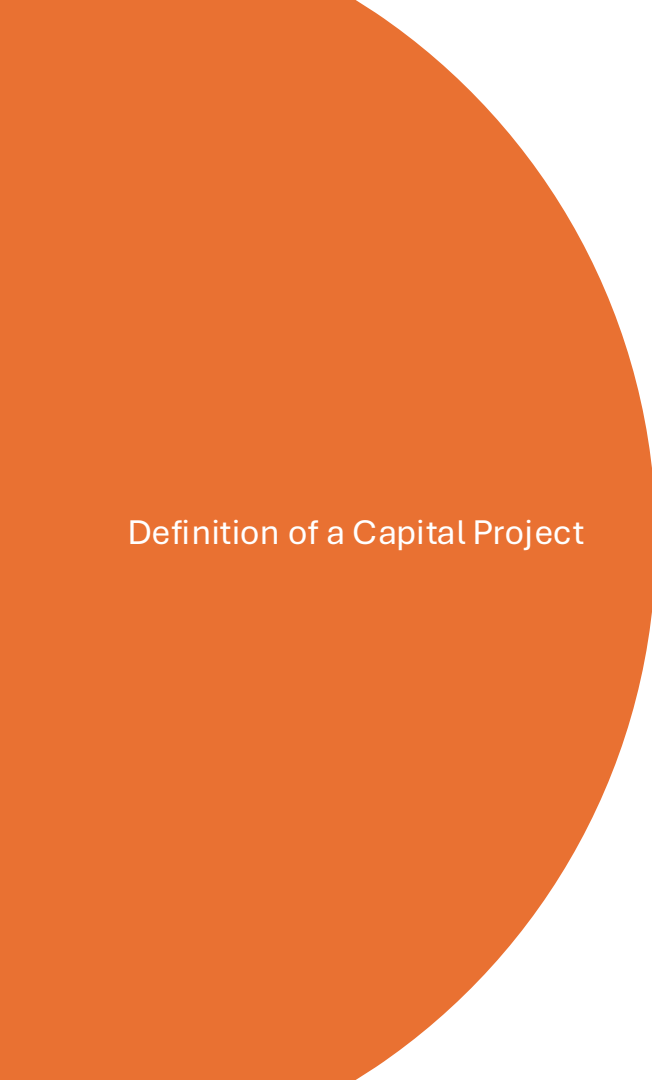


Act 1 – Capital Context

Core Message:

CQV Operates within a larger capital delivery system

**CQV Project Costs
= Baseline Effort + Interpretation + Rework**

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Definition of a Capital Project

A Capital project is a long-term capital investment intended to build, add to, or improve a capital asset characterized by its large scale and high-cost relative to other investments.



How Big are Modern Mega Capital Projects?

J&J \$2 B build in Wilson, NC

Lily \$27 B across 4 mega sites

Amgen \$1 B in Holly Springs, NC

Sanofi \$2.5 B for Insulin production in
Germany and China

Sanofi \$1 B in Vitry-sur-Siène

Novo Nordisk \$4.1 B in North Carolina

Capital Project Structure: Engineering



Feasibility



Basic Design



Detail Design



Construction



Startup and Commissioning



Qualification



Validation

Industry Benchmark: Capital Project Schedule

Schedule Duration as % of Total Project Duration			
	Low	Average	High
Basic Design	8	10	12
Detail Design	17	24	33
Construction	40	55	61
Startup and Commissioning	18	22	30
Qualification	13	16	21
Validation	3	4	5

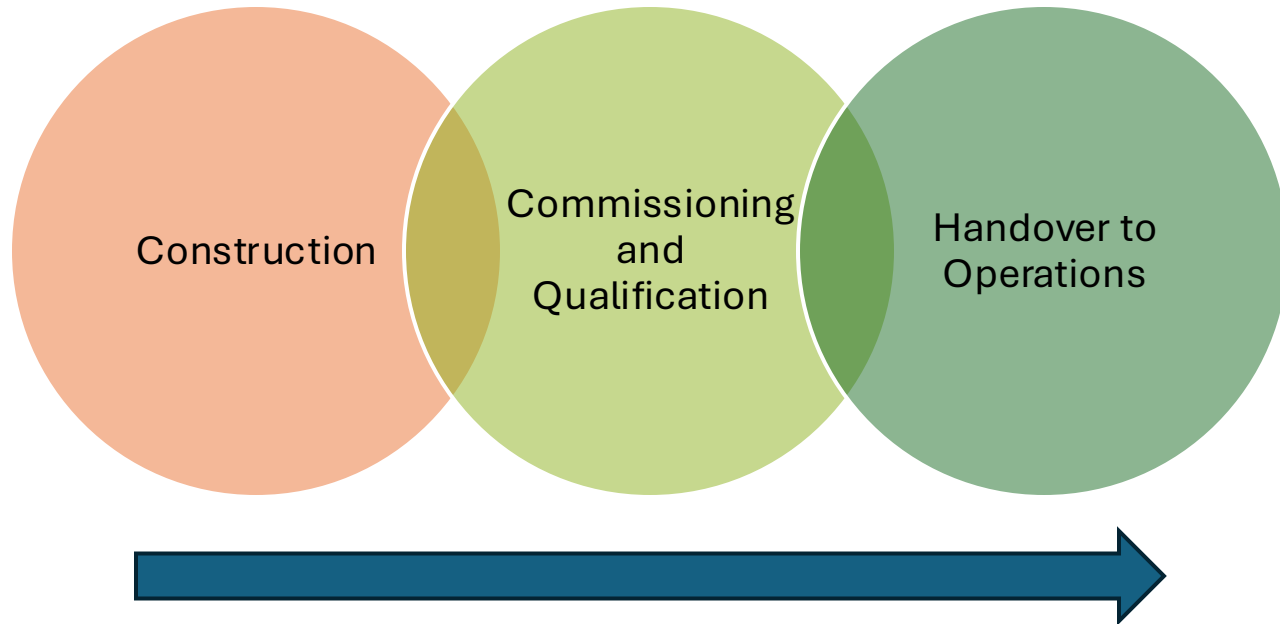
- [How data can improve pharmaceutical construction project performance | Turner & Townsend \(turnerandtownsend.com\)](https://turnerandtownsend.com)

Industry Benchmark: Capital Project Costs

Cost as % of Total Project Cost			
	Low	Average	High
Engineering	5.5	12	25
Construction Management	3.5	12.5	24.5
General Conditions	0.5	4.5	12.5
Process Equipment/Piping	15.5	30.5	43.5
Clean/Process Utilities	1	5.5	18
Mechanical/Electrical/Plumbing (MEP)	3	7.5	17.5
Civil Structural/Architectural	4.5	13.5	32.5
Automation	1	3	10
Commissioning and Qualification	.5	4	11
Electrical and Instrumentation	1	6.5	11.5

- [How data can improve pharmaceutical construction project performance | Turner & Townsend \(turnerandtownsend.com\)](https://turnerandtownsend.com)

Typical Construction and C&Q Workflow



Typical C&Q Digital Savings



DIGITAL CONTENT

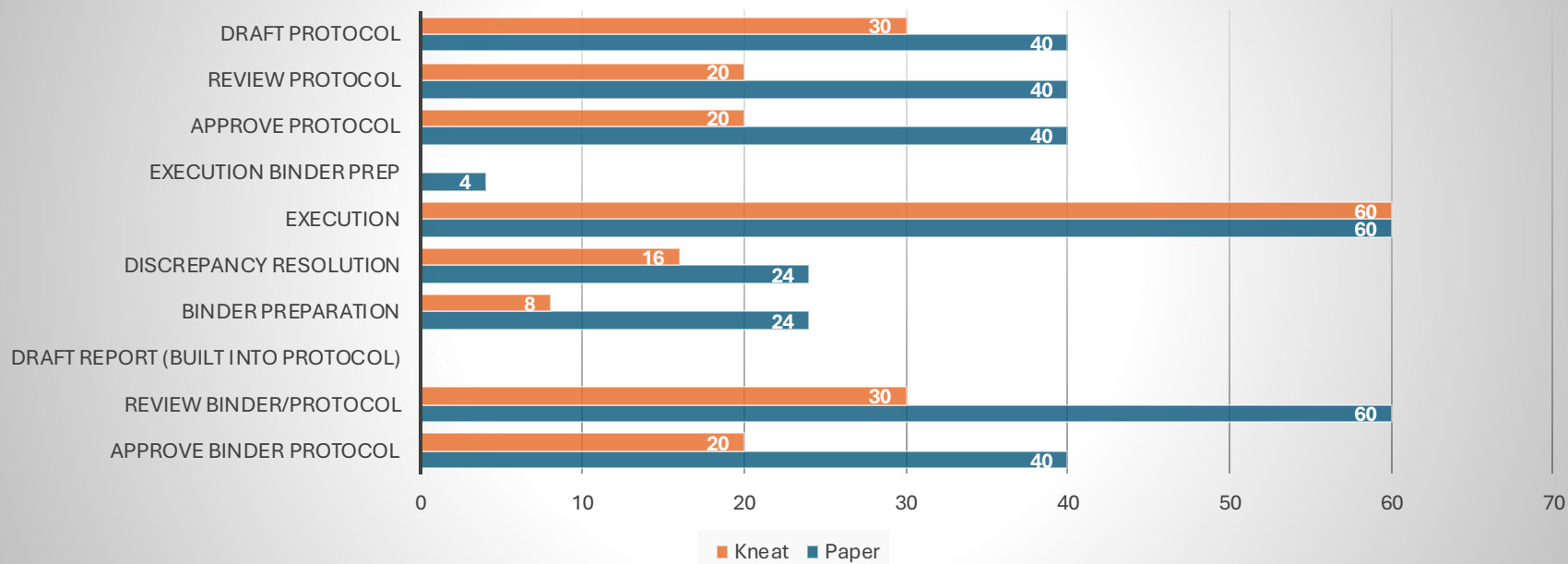


DIGITAL EXECUTION

C&Q Savings Using Kneat

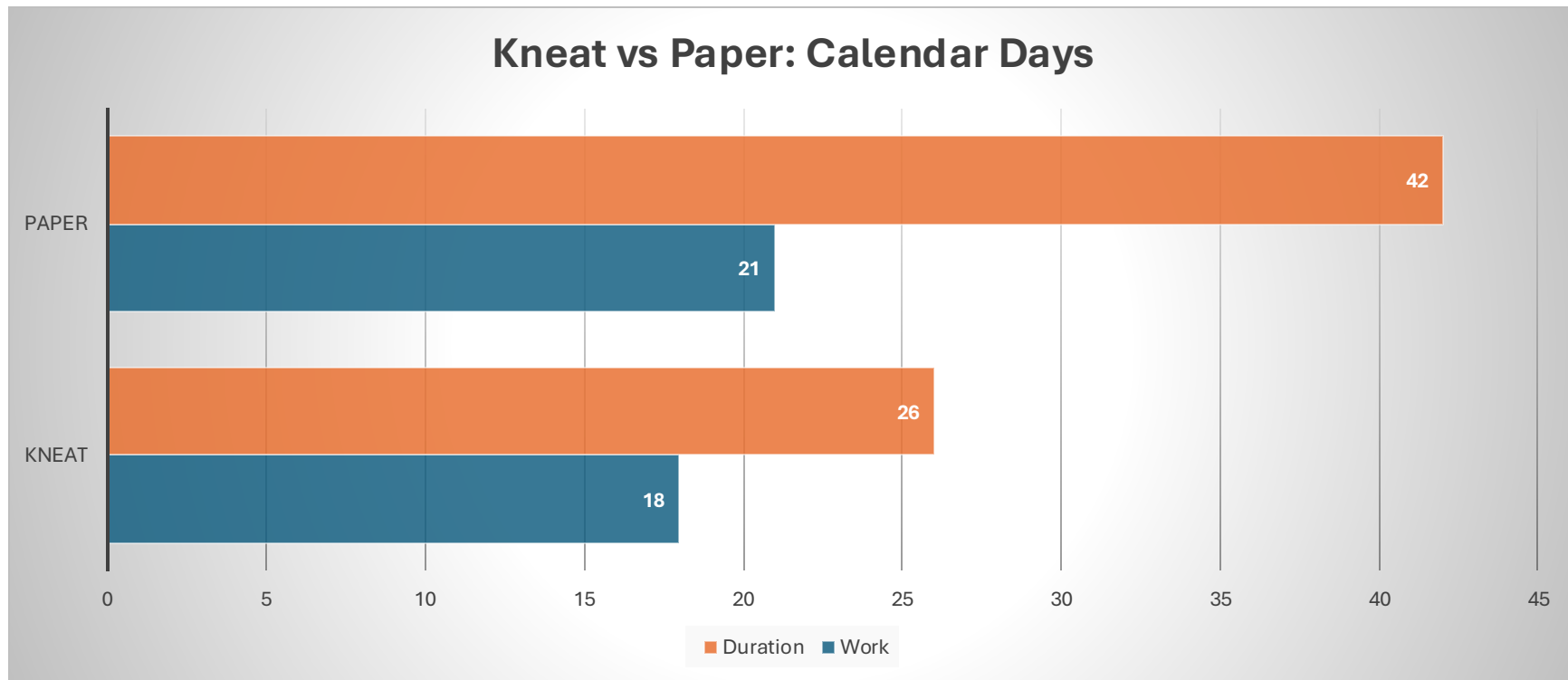
Comparison

Kneat vs. Paper Comparison (Calendar Hours)



C&Q Savings Using Kneat

Comparison

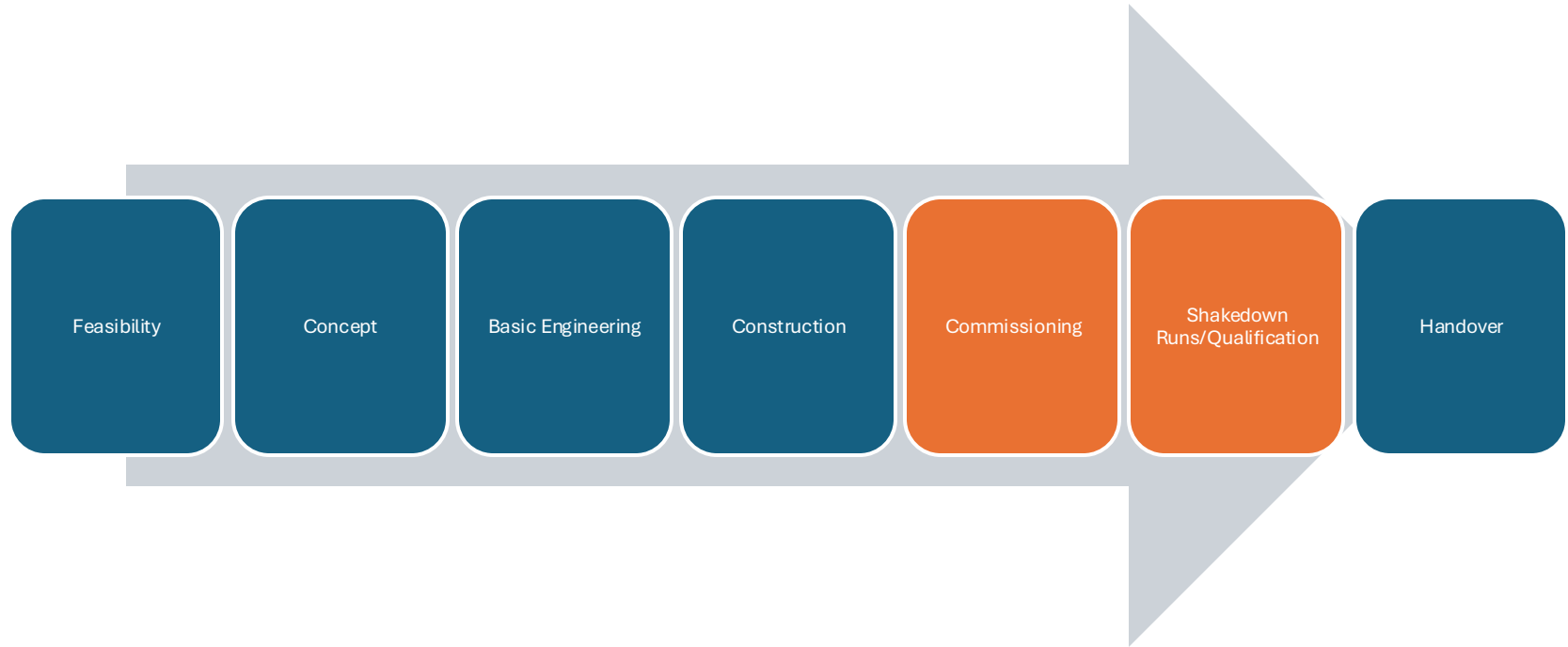


Typical C&Q Digital Savings Over Time

Content	Paper	2019	2022	2025
Complex Equipment Protocol	50-60 hours	30-40 hours	10-15 hours	< 4 hours
Protocol Clone	5-10 hours	< 5 hours	< 2-3 hours	minutes



Typical Engineering Project Workflow



Typical C&Q in Engineering Digital Savings



Integrated documents
Across Engineering Lifecycle
and C&Q Documents



Digital Leveraging Strategies



Digital Engineering Change
Management

Typical C&Q in Project Management Digital Savings



Pacing with Construction

Where are future digital C&Q Savings?



Steering Committee



Project Management



Engineering



Quality



Finance

Meet Project Controls



Project Controls

“All Commissioning and Qualification activities supporting large Capital Projects must be digitized.”

Act 2 – Core Problem in CQV

Core Perception:

“Why is CQV always late and over budget?”

Core Message:

CQV reveals issues late in the project lifecycle, and it is this timing that drives rework, cost, and schedule amplification.

CQV Project Costs
= Baseline Effort + Interpretation + Rework

CQV Occurs at the Point of Integration

- CQV is where systems are tested together and real performance is confirmed.
 - Design and construction is complete
 - Automation is deployed
 - Testing happens under real conditions across disciplines





CQV and Late Discovery

- When issues are discovered late, the resulting rework drives cost and schedule amplification
 - Issues are identified only at execution
 - Resolution requires investigation, correction, and retesting
 - Work already completed may need to be revisited
 - Impact increases as the project approaches completion

Is Protocol Centric Enough?

- Protocol Centric CQV – paper based or digital – performs well as an expression of ISPE Baseline Guidance for Commissioning and Qualification, or Annex 15, and others.
- The pace of today's capital projects, and the tolerance for issues discovered in CQV, is demanding that we do more, faster, and with less.
- Can we do better?



Act 3 – Interpretation and Translation

Core Message:

Interpretation is a major embedded component of CQV work.

CQV Project Costs
= Baseline Effort + Interpretation + Rework

Interpretation as Digital Topic of Interest

- Recent AI partnered workflows demonstrate that interpretation effort can be reduced
- Separating interpretation from baseline effort and rework is the first step in applying new digital technologies in CQV



CQV Work Includes Significant Interpretation

- MSAT translates scientific conclusions into therapeutic promises.
- Engineering translates business needs into technical solutions
- CQV Translates technical solutions into a compliance solutions
- **Interpretation and translation in Biotech and Pharma is our foundational activity.**



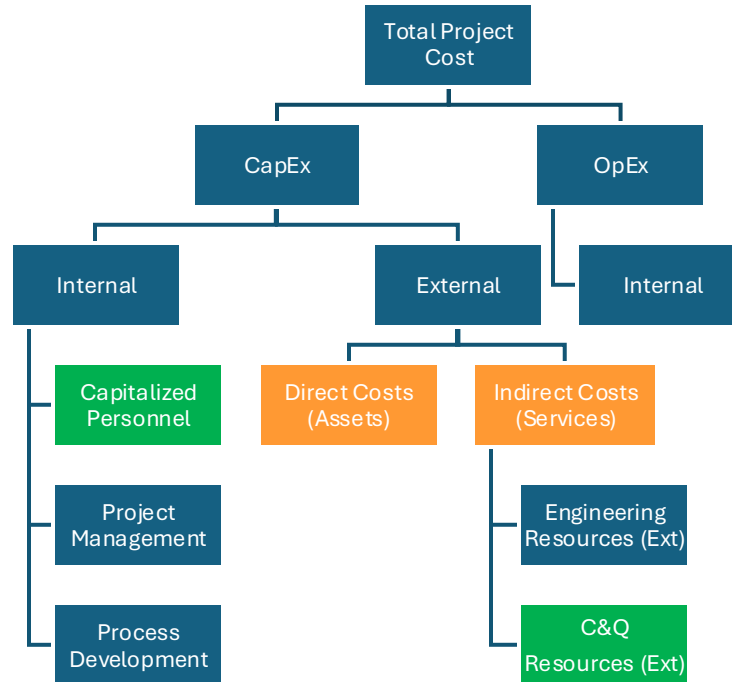
Act 4 – Measurement

Core Message:

Earned Value Management (EVM) is the key approach that successful project managers and project controls professionals use to assess the health of a project.

CQV Project Costs
= Baseline Effort + Interpretation + Rework

Project Controls Finance Hierarchy (Simplified)



Patrick's Metrics for Project C&Q

- Total Cost of C&Q as a Percentage of a Project's Direct Costs
- Cost per Protocol



C&Q Savings in Project Controls

- Benchmarking Resources
- Monitoring Execution Progress
- Performance Comparisons Across Projects
- Evaluating the strength of a C&Q services proposal

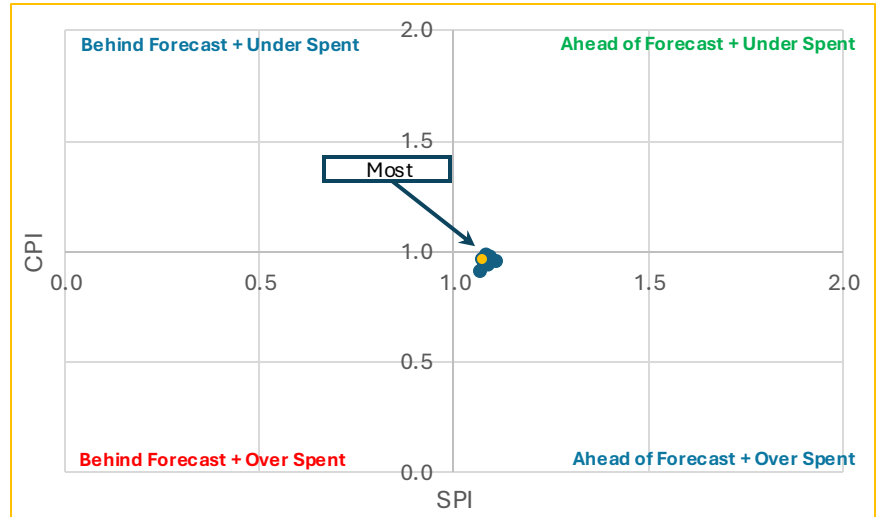
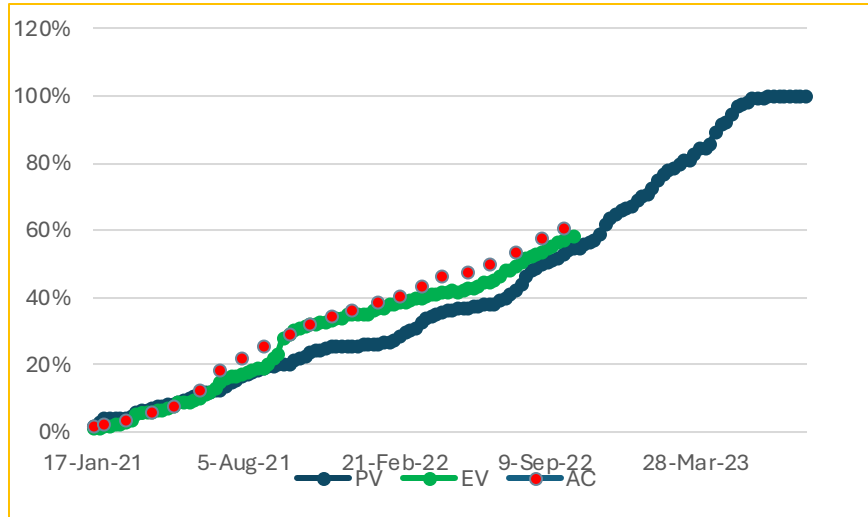


Benchmarking Resources

- “How long will it take to commission and qualify these assets?”
- Project Management wants to know how long.
- Project controls wants to know how many resources.

Resources Required	21 +												
	20												
	19												
	18												
	17												
	16												
	15												
	14												
	13												
	12												
	11												
	10												
	9												
	8												
	7												
	6												
	5												
	4												
	3												
	2												
	1												
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	
Work Hours	168	152	168	176	176	160	176	176	160	176	152	168	
Total Hours	168	320	488	664	840	1000	1176	1352	1512	1688	1840	2008	
# Resources	42	22	14	11	8	7	6	5	5	4	4	3	

Monitoring Progress – Earned Value Analysis



Act 5 – Digital CQV

Core Message:

Digital CQV improves execution structure and visibility

CQV Project Costs
= Baseline Effort + Interpretation + Rework

Digital CQV Today

- We have come a long way in a few short years
 - Paper to Glass
 - Templates and Libraries
 - Reuse and Cloning
 - Rigid Data Integrity Rules
 - Inspection Readiness
- **Key Message:** Digital CQV has improved execution and enabled reuse, reducing both variability and baseline effort.

Act 6 – Structured Data

Core Message:

Structured data reduces interpretation at its source

CQV Project Costs
= Baseline Effort + Interpretation + Rework

What is Structured Data?

- In a CQV context, structured data means capturing key information – in structures called entities in Kneat – in a consistent and reusable format.
 - The original intended use of entities was to facilitate retrieval and sharing of data across a lifecycle workflow – and to report out on the qualified state of a system or process.
 - In a new development, driven by AI, structured data can also be used to facilitate and significantly reduce interpretation in the CQV space.



Example of Structured Data In Use

Structured Data (Entities)

- System
- Equipment
- Requirement
- Test Case
- Risk

Interpreted Data

- User Requirements
- System Impact Assignment
- System Risk Classifications
- Execution strategies

Generated Outputs

- URS
- SIA/SRA
- Protocol/Reports
- Trace Matrixes

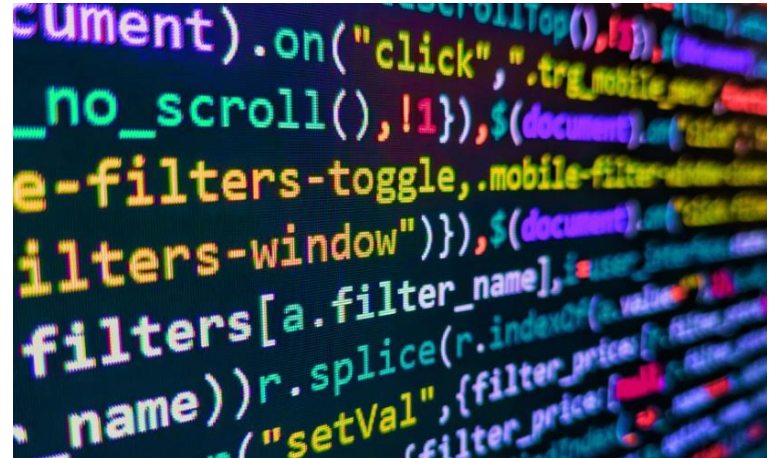
How Structured Data Reduces Typical AI Limitations

- Gen AI is effective at interpreting information, but its reliability depends on how the information is structured and provided.
 - Context limitations can lead to drift across long workflows
 - Information is often stored in documents or images – not structured formats – and is subject to additional layers of interpretation
 - Retrieval across multiple documents can be inconsistent
 - Output clarity depends on clarity and consistency of inputs



Machine Readable Content Enables Consistent Interpretation at Scale

- Machine readable formats make structured CQV data directly usable across systems, enabling consistent and repeatable interpretation.
 - Human readable documents require repeated interpretation
 - Machine-readable formats preserve structure and relationships
 - Enables consistent generation and reuse of CQV content



Act 7 – Future Trajectory

Core Message:

Interpretation becomes increasingly compressible

CQV Project Costs
= Baseline Effort + Interpretation + Rework

From Document Centric to Data Centric

- In review, CQV today is now evolving from document centric to data centric workflows built on structured lifecycle information.
 - Documents become outputs, not primary work products
 - Lifecycle data drives requirements, risk, and testing
 - Interpretation, now separated from the baseline CQV work product, is now highlighted as a significant cost saving opportunity.



Impact to Capital Projects

- A data driven CQV model, empowered with digital interpretation strategies, enables more consistent, efficient, and predictable project delivery.

- More consistent document generation across the lifecycle
- Reduced duplication and rework
- Improved alignment between design, risk, and testing
- Shortened, and more predictable, baselines



Act 8 – Capital Impact

Core Message:

Evolving CQV data structures enable meaningful cost reduction

CQV Project Costs
= Baseline Effort + Interpretation + Rework

Two Paths When We Thought There Was Only One

2025:

Reporting-Focused
Adoption of Structured
Data

- Data lakes, Dashboards
- Improved Visibility and Tracking
- Better Reporting
- Limited Cost Improvements

2026 and beyond:

Managed Interpretation
with Structured Data

- Interpretation captured once and reused
- Lifecycle documents generated from structured inputs
- Reduced duplication and inconsistency
- Improved baselining and execution



Driving Down Cost in Capital Projects

- CQV cost reduction depends on how we structure and manage the work – not just how we execute it.
- Today: Protocol Centric CQV (Digital)
 - Interpretation repeated across the lifecycle
 - Limited data extraction
 - Limited alignment with measurement (EVM)
 - **Outcome: 5-7% of direct project cost**
- Incremental Improvement with Data Centric Only Approach
 - Entity enabled elements
 - Better data available for reporting and dashboards
 - Improved visibility (e.g. real time RTM tracking)
 - **Outcome: 4-5% of direct project cost**
- Structured Data and Managed Interpretation
 - Interpretation captured once and reused
 - Machine-readable lifecycle data
 - Consistent AI document generation
 - Improved baselining and execution
 - **Outcome: 3-4% of direct project cost**

Questions:



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