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Building Apps Made Easy: From R Shiny to Organizational Impact

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of GSK.*



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The real challenge is not creating the app

Coding barrier ↓

Adoption ≠ Guaranteed

Sustainable use ↑

- Generative AI + Open-Source Technology make prototyping dramatically easier.
- But an organizational tool must also be understandable, testable, supportable and replaceable.
- Today: how far should we go for non-GxP applications used in our business?

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3 Application classes

Class	Example	Scope	Approach
1. Study-specific / Small group use / Non-GxP	Prohibited concomitant medication viewer for Study-001	One study / Small group use	Simple validation / QC
2. Cross-study support / Organizational use / Non-GxP	CDISC QC, data exploration, utility tools	All studies / Organizational use	More testing + UAT
3. GxP / IT-managed	Production analysis systems	All studies	GxP + CSV + IT governance - OUT OF SCOPE

Key principle: validation effort should follow intended use + risk, not the fact that it is written in R.

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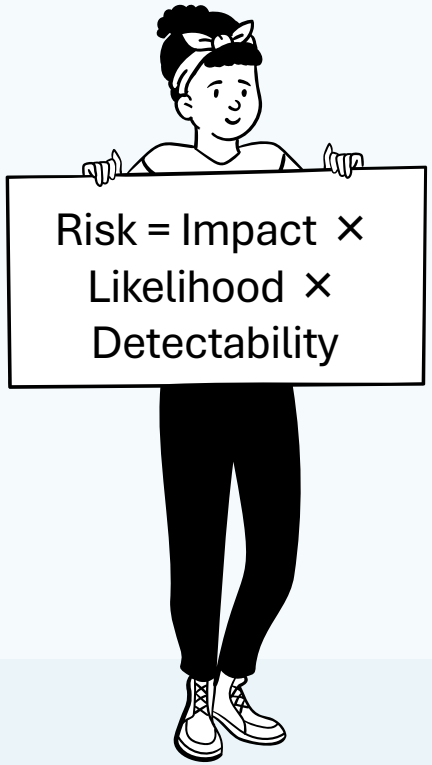
Risk-based question: “What can go wrong?”

- Could a wrong result change a clinical conclusion or a business decision?
- Is the application the authoritative source, or only a convenience / support tool?
- Will the result be independently verified before it is used?
- How broad is the impact: one study, every study or your organization?
- How easy is it to detect and recover from an error?



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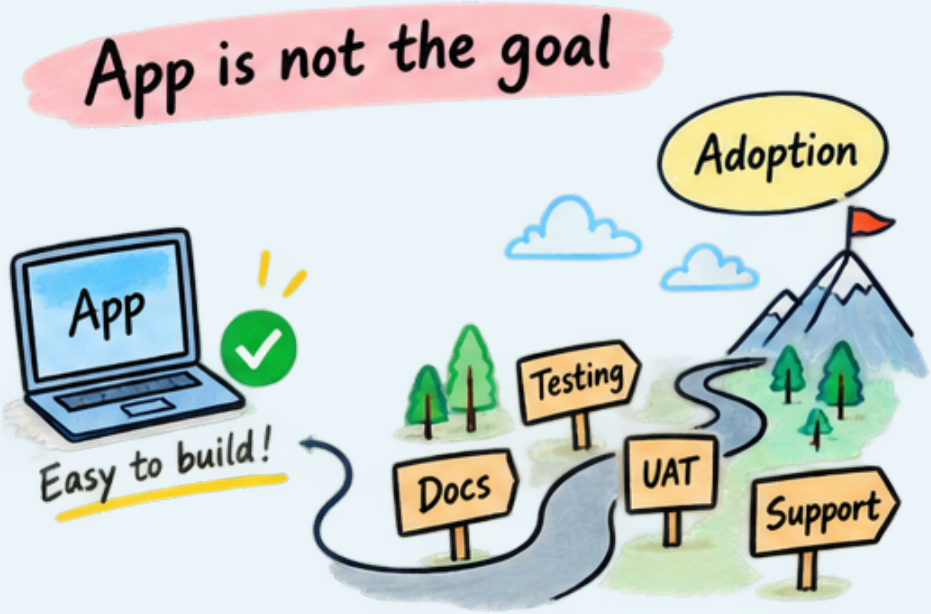
Recommended lifecycle for R Shiny applications

1. Define intended use
2. Risk assessment
3. Requirement
4. Develop
5. Test
6. UAT
7. Release
8. Maintain, Support

- Ensure the evidence is proportionate.
- Enough to show that the intended use works.
- Not a miniature GxP validation package.



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Testing vocabulary: Software testing vs. CSV

Activity	Typical target	Main question
Unit Test	Individual function/module	Does each building block behave correctly?
Integration Test	Interfaces between modules	Do components work together?
System Test	Whole application	Does the complete system meet requirements?
Acceptance Test / UAT	User/business acceptance	Can intended users perform real tasks and accept the result?
CSV (GxP)	Regulated computerized system	Documented evidence that a system is fit for intended use in its regulated context

For non-GxP tools, software testing + documented user acceptance can be sufficient.
CSV terminology is not automatically required.

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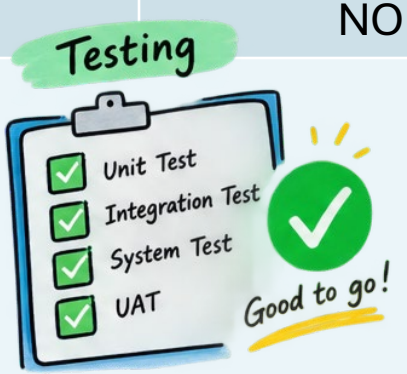
Test strategy: What should we test?

Test	Focus	Class 1	Class 2
Functional / Unit	Core calculations, filters, transformations	YES	YES
Integration	Module-to-module interfaces	Usually targeted	Targeted
System	End-to-end user workflow	YES, lightweight	YES
Acceptance / UAT	Real user scenarios	YES	YES
Regression	Changes do not break existing functions	As needed	As needed
Performance	Load/stress/response under many users	As needed*	As needed*
Security	Penetration / threat testing	Usually NO	Risk-based
Cross-browser / OS	Different platforms	Usually NO	Usually NO
Monkey / random testing	Unexpected arbitrary interactions	NO	NO

- For example: If the application loads CDISC datasets with more than 10 GB.



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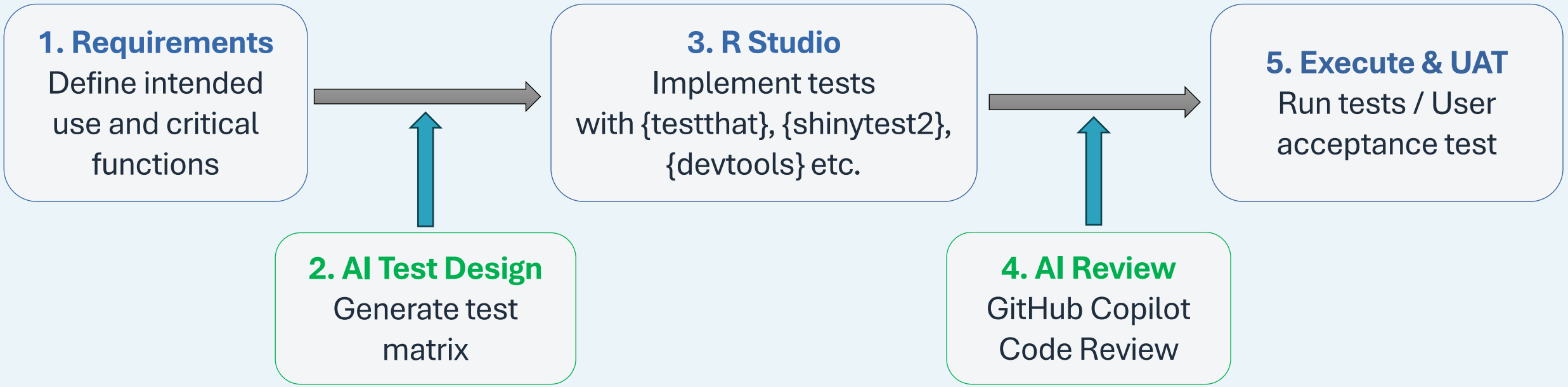
Test Workflow: GitHub + R Studio + AI



AI is useful for

- Generating many plausible test scenarios
- Finding boundary / invalid-input cases
- Explaining unfamiliar code and test failures

Human responsibility

- Define what “correct” means
- Independently verify important expected results
- Approve test evidence and release decision

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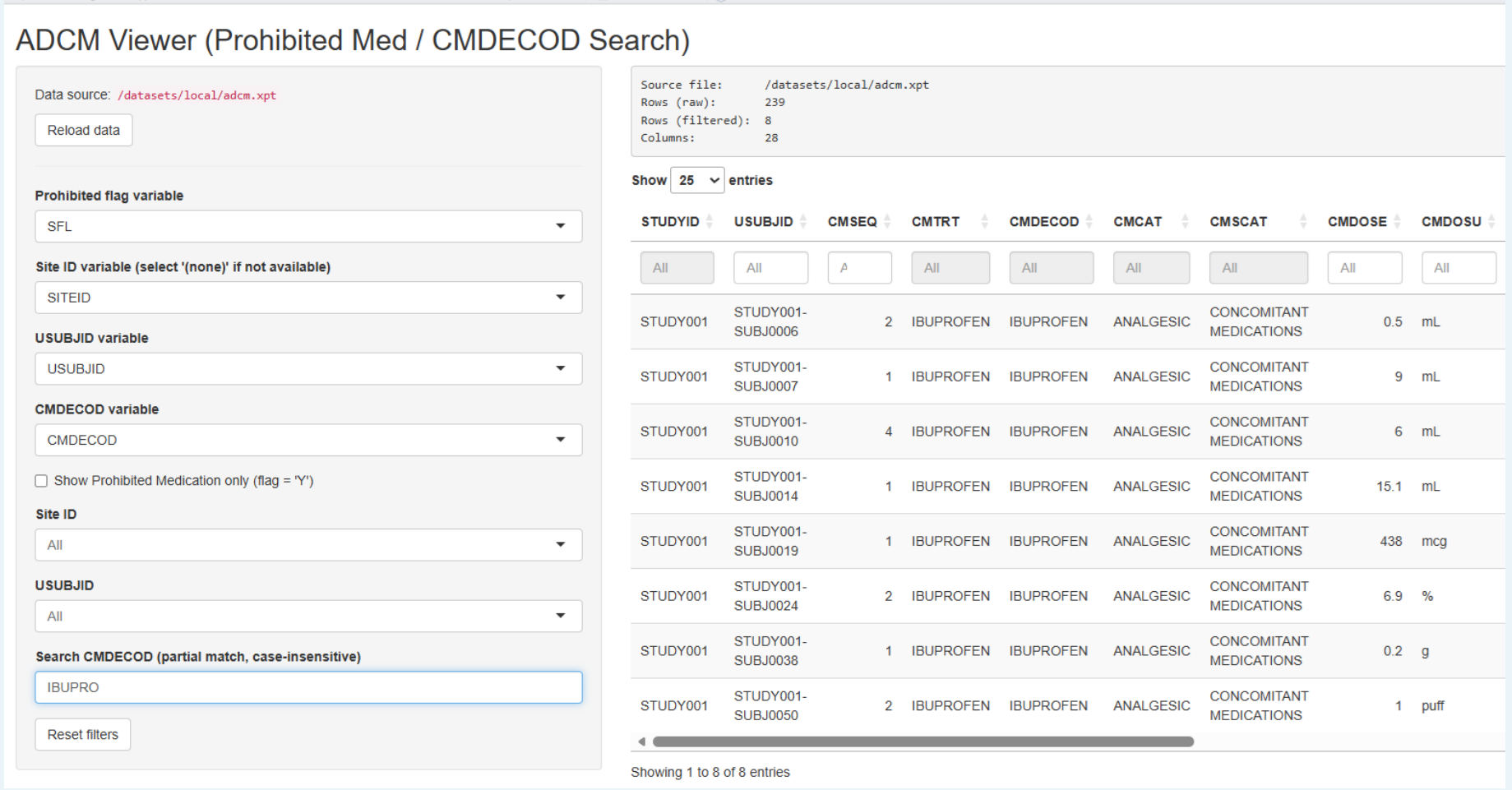
Class 1: Study-specific / Small group use

Class 1 application example: Data viewer for prohibited concomitant medications



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Example of Class 1: Data viewer for prohibited concomitant medications

- Example: Data viewer for prohibited concomitant medications.
  - Compared to Excel, the advantages of R Shiny Application are: 1. Ability to manage access permissions, 2. No possibility of data modification or manipulation, 3. Once deployed, only data updates are required.
- Formal identification is performed elsewhere (e.g., double programming, data review meeting).
- Therefore, the Shiny app is a viewing and navigation aid, not the decision engine.
- Minimum evidence should demonstrate: correct data load, correct display, filtering/search, key labels, missing values, and obvious error handling.



Suggested evidence: Developer test checklist + Small set of expected-result test cases + User confirmation

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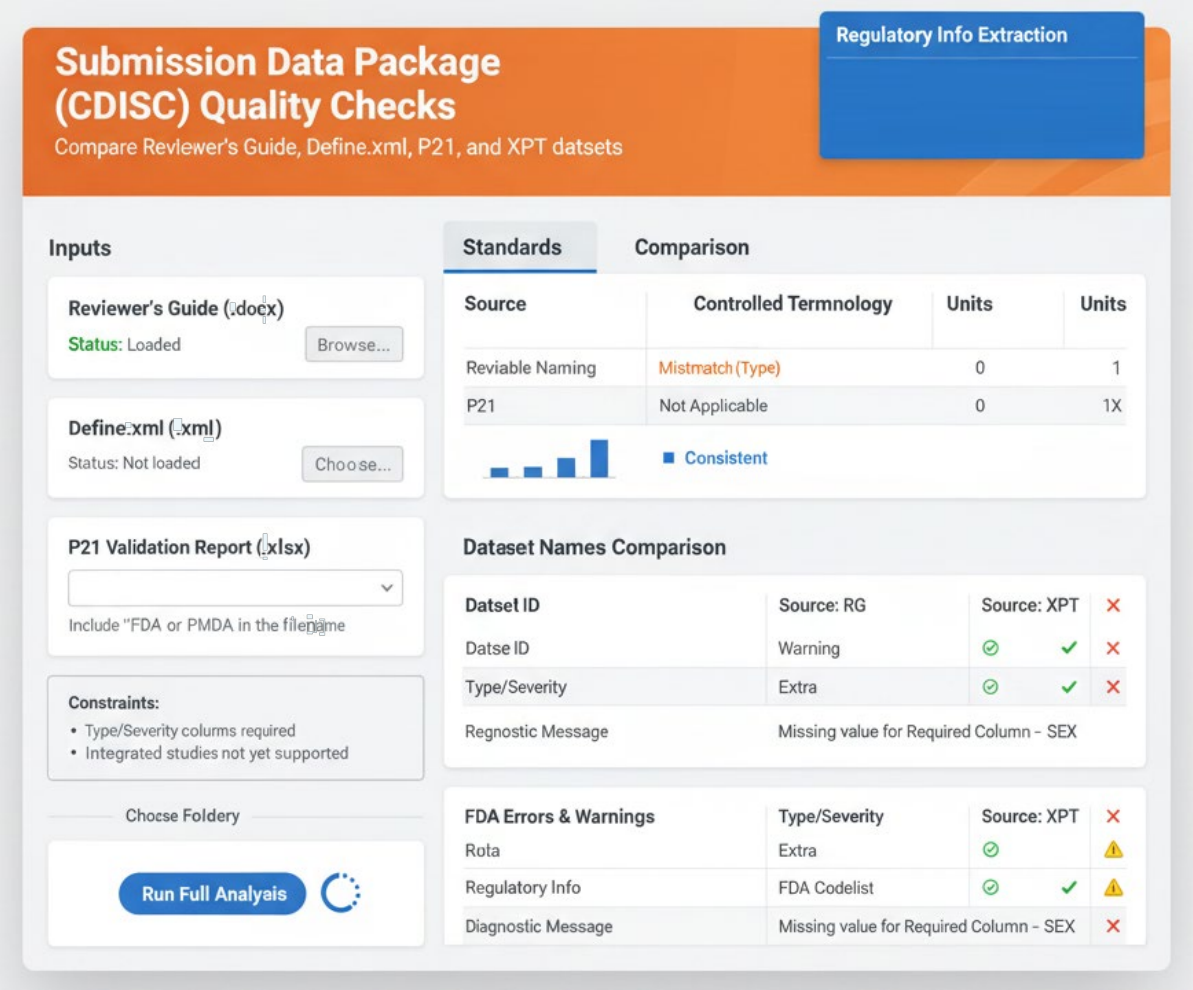
Class 2: Cross-study / Organizational use

Class 2 application Example: CDISC package QC application used across multiple clinical studies.



This is just sample image.

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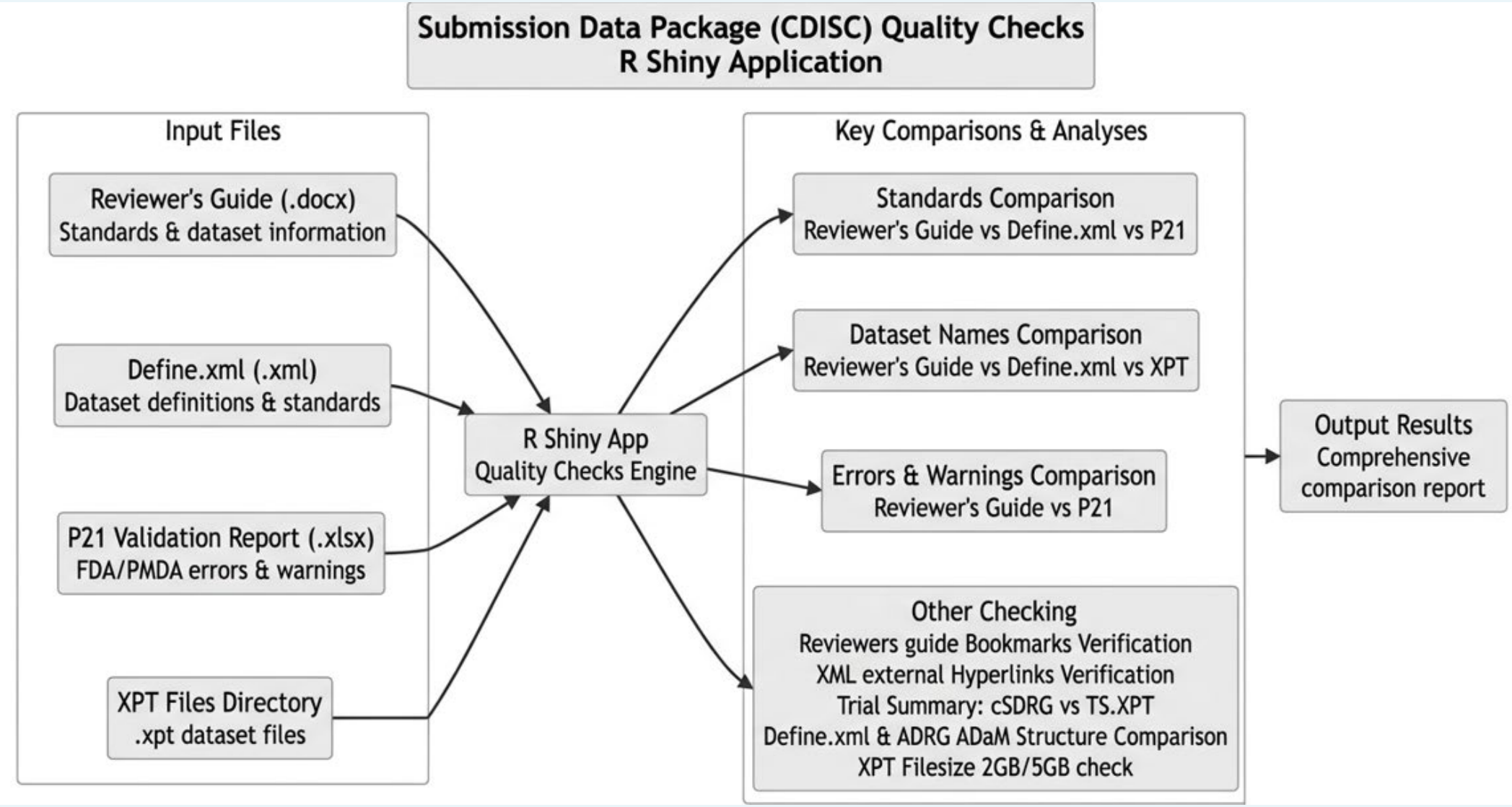
Mermaid diagram: CDISC package QC application



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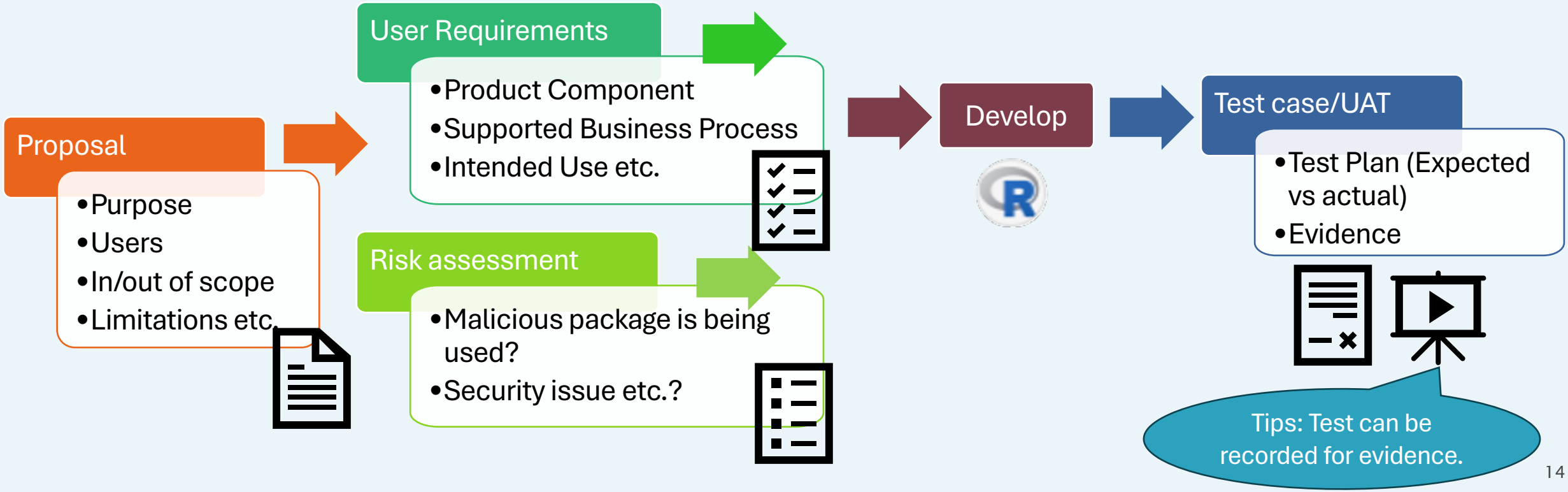
Example of Class 2: CDISC package QC

- Example: CDISC package QC application used across multiple clinical studies.
- As one defect can affect many studies, test depth should increase even when the app is not GxP.
- Formal QC remains outside the app; the app should clearly state that it is a support tool.



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Impact and Lessons Learned

- Impact:
  - CDISC packages review time saving (e.g., 20 hours manual review/QC per study) / Accelerate Timelines / Boost Quality & Consistency
- Lessons Learned:
  - Processing and extracting .docx (ADRG/cSDRG) are not straight forward as its unstructured data.
  - Utilizing AI for this unstructured data might yield better results.
  - During the Errors & Warnings comparison, there are the issue of Rule ID not being in many studies because it is not included in the PHUSE template.



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The hidden risk: “The developer is the support model”

- Applications often start as personal productivity tools.
- Then they become widely used while knowledge remains in one person's head.
- Risks: staff turnover, package changes, expired credentials, undocumented business rules, no one able to rebuild the app.
- Organizational impact therefore depends on ownership, not just code quality.

Bus factor = 1 → Operational risk

The “Bus factor” is a measurement of the risk resulting from information and capabilities not being shared among team members, derived from the phrase "in case they get hit by a bus". “Bus factor = 1” means one person holds critical knowledge; the project is essentially failed if he/she disappears.

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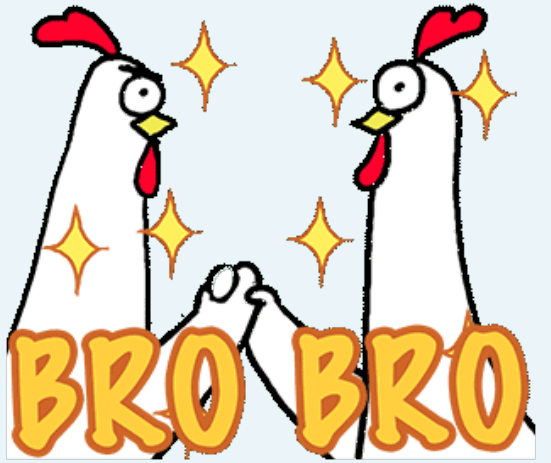
A pragmatic support model for Class 1–2

Role	Responsibility	Minimum
Business owner	Defines intended use, priority, acceptance	Required
Technical owner	Code, dependencies, release, troubleshooting	Required
Backup owner	Can maintain/release without the primary owner	Strongly recommended
IT / platform contact	Hosting, access, infrastructure escalation	As needed
Users	Feedback, incidents, UAT participation	Required

Class 1: Business owner and Technical Owner may be a same person, but archive code + test evidence + handover notes for backup owner. IT contact may not be needed.

Class 2: Establish a small “application owner” community / registry and mandatory backup.



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Key Take-Home Messages



Easy development changes the bottleneck from coding to governance and adoption.



Define intended use and risk first; then choose the minimum effective test set.



Class 1 can be lightweight. Class 2 needs broader testing and UAT.



Document enough to reproduce, test and hand over the application.



Ownership, support and communication make the application sustainable.

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Thank you for your attention!



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What about DQ / IQ / OQ / PQ?

Term	Typical question	Context
DQ: Design Qualification	Does the design meet predefined requirements?	CSV / validation context
IQ: Installation Qualification	Was the system installed correctly?	CSV / infrastructure context
OQ: Operational Qualification	Does it operate as specified?	CSV / regulated context
PQ: Performance Qualification	Does it perform in the real process?	CSV / regulated context
Non-GxP Shiny	Software testing + UAT + appropriate records	Use proportionate controls

For this presentation, Class 1 and 2 are non-GxP applications: formal DQ/IQ/OQ/PQ is not the objective.