

Check Yourself:

Edit Checks and Queries Made Easy with Shiny

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Overview



Introduction and Challenges



Why Shiny?



Solution Overview



Core Features



Results and Future Directions



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Clinical Trials Data Review: Complex, Manual, Fragmented

Data completeness and accuracy underpins every clinical and regulatory decision

- DM teams safeguard integrity through discrepancy detection, query resolution, and compliance with CDISC and 21 CFR Part 11.
- Traditional tools have served well but are slow to iterate, inconsistent and difficult to scale.
- Trial data now streams from EDC, labs, ePRO, wearables, and external sources, driving exponential growth in volume and complexity.
- Regulatory expectations demand documented, auditable, and reproducible data review processes.

*Clinical data cleaning workflows need automation, transparency, and real-time interactivity,
not more spreadsheets!*

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Why Shiny? From Static Listings to Intelligent Interaction

Data Review Should Be Living, Not Static

- Transforms static listings into interactive, intelligent reviews empowering teams to explore, validate, and resolve issues in real time.
- Tailors to your workflow with customizable validation rules, dynamic visualizations and drill-downs, and automated query logic, no more one-size-fits-all tools.
- Built on R's open-source power for transparency, scalability, and seamless integration with existing analytics pipelines.
- Future-ready foundation for AI-driven anomaly detection and predictive quality insights.

*Utilizing Shiny enables a faster, smarter, and more adaptive approach to data quality,
turning review from a task into an intelligent process.*

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From user insight to an intelligent, modular solution

- Developed a Proof-of-Concept Shiny application enabling end-to-end data cleaning, faster, smarter, and tailored to user workflows.
- Partnered closely with our Data Management team to understand real-world challenges in data review and cleaning.
- Used raw data with configurable rule definitions to automate edit checks and query generation.
- Built on four core layers ensuring scalability, compliance, and performance:
[Data Ingestion](#) | [Visualization](#) | [Rule Engine](#) | [Query Module](#)
- Interoperable with EDC, metadata repositories, and issue trackers via REST APIs and standardized exports.

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DRT: A Modular Shiny App. for Edit Checks and Queries

A unified, interactive framework that transforms manual review into an agile, data-driven process aligned with regulatory and operational needs.

Technical Foundations:

- Reactive programming & server-side processing
- Role-based access and audit logging
- CI/CD with Docker for reproducibility

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Controlled Study Access

Data Review Tool <

Home
Study Overview
Patient Profile

STUDY
NATEVBA_DATA

RECORDS
2372

252
OPEN

5
ANSWERED

97
CLOSED

7

Dynamic Filters and Drill Downs

Data Review Tool <

Home
Study Overview
Patient Profile

Natevba_Data

Enrolled: 66 In Screening: 3 Pre Screen: 1 Screen Failure: 1 Withdrawn: 4

Domain	Queries																
AE	30 28 10 1 35																
NAME	STUDY	STUDYNAME	SITEMUM	SUBJID	AETERM	PT	SOC	AESTRTDT	AENDAT	AESR	AESD	AESD	AESD	AESD	AESD	AESD	AESD
NAME	STUDY	STUDYNAME	SITEMUM	SUBJID	AETERM	PT	SOC	AESTRTDT	AENDAT	AESR	AESD	AESD	AESD	AESD	AESD	AESD	AESD
US-101	US-101-0001	Populaceon	-	-	2020-06-02	-	N	N	NOT RECOVERED/NOT RECOVERED	1	N	DOSE NOT CHANGED					
US-101	US-101-0001	headaches	-	-	2020-07-16	2020-07-16	N	N	RECOVERED/OLIVED	7	Y	NOT APPLICABLE					
Natevba_Data	US-101-0001	reflux	Refux gastritis	Gastrointestinal disorders	2020-07-16	-	Y	Y	RECOVERED/OLIVED	1	N	DOSE NOT CHANGED					
Natevba_Data	US-101-0001	Pneumonia	-	-	2020-07-22	2020-01-01	Y	Y	FATAL	5	Y	DRUG WITHDRAWN					
Natevba_Data	US-101-0001	Ovarian Cyst	-	-	2020-07-23	-	N	N	RECOVERED/OLIVED	2	N	UNKNOWN					
Natevba_Data	US-101-0002	migraine	Migraine	Nervous system disorders	2020-05-20	2020-05-30	N	-	-	1	-	-					

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[illegible]

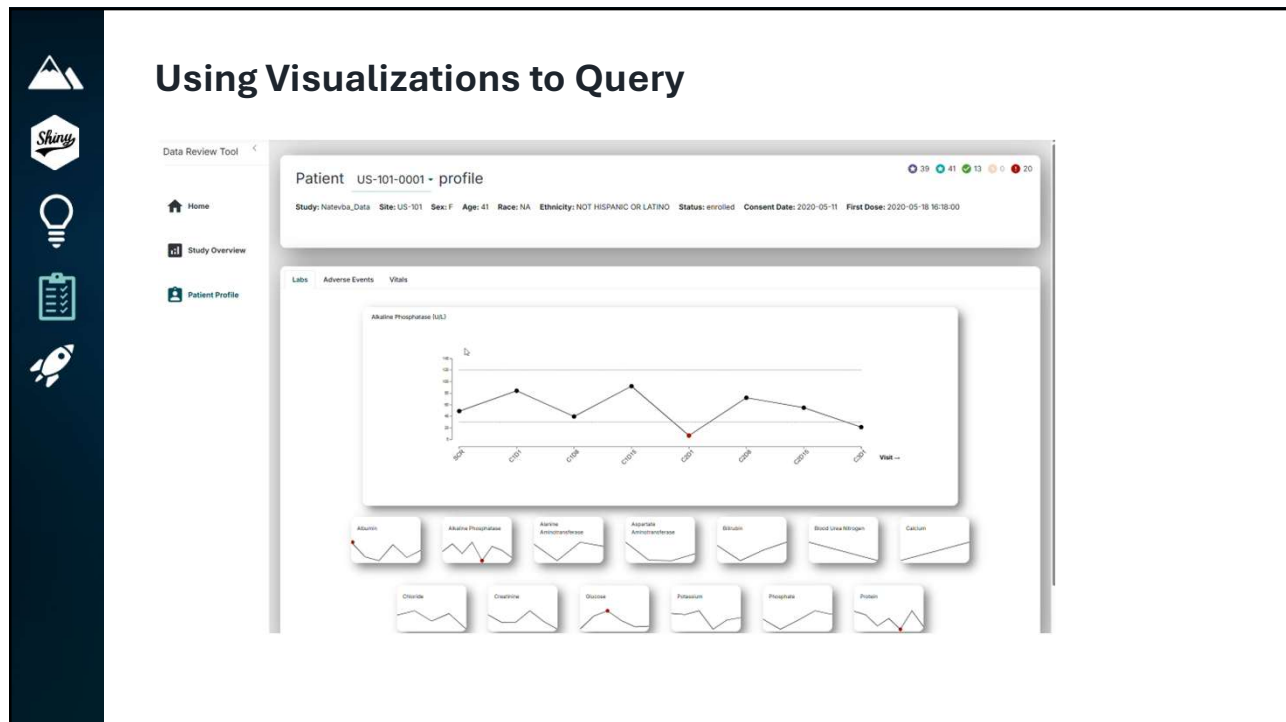
[illegible]

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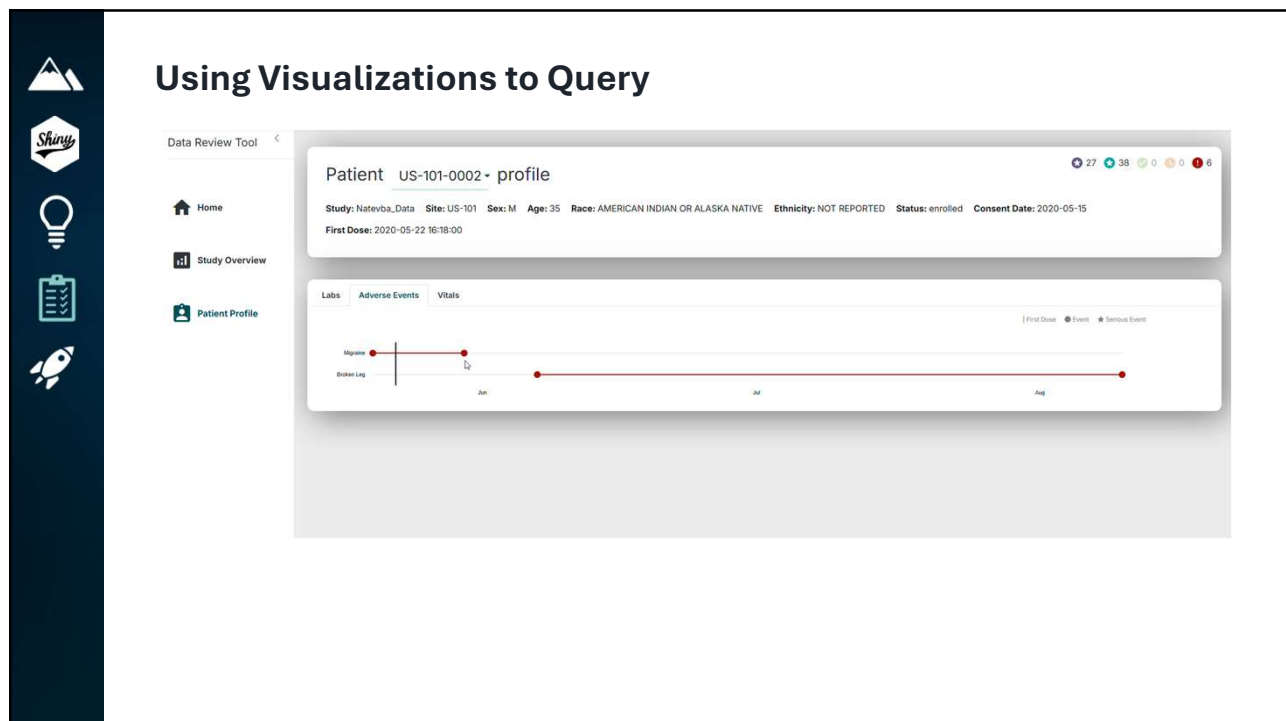
The screenshot displays the Shinyr Data Review Tool interface. On the left is a dark sidebar with icons for Home, Study Overview, Patient Profile, and a rocket icon. The main content area is titled 'Data Review Tool' and shows a study named 'Natevba_Data'. Below the title, it lists counts: 'Enrolled: 66', 'In Screening: 3', 'Pre Screen: 1', 'Screen Failure: 1', and 'Withdrawn: 4'. The interface is divided into 'Domain' and 'Queries' tabs. The 'Queries' tab is active, showing a table with columns: Row, STAT, STUDYNAME, SYSTEM, SUBID, SEX, AGE, BIRTHDAY, ETHNIC, RACE, RACEETH, CHILDST, MREASTHT, LBPRE, PREL_LBORNS, LBOT, and Specimen Collection. A modal dialog box titled 'No Queries' is open, with a sub-header 'Open a Query' and a text input field labeled 'Compose Query' with the placeholder 'Please type your query here'. The dialog has 'Submit' and 'Cancel' buttons. The background table shows data rows with various colored cells (green, red, orange) indicating different statuses or results.

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The screenshot displays the Shiny Data Review Tool interface. On the left is a dark blue sidebar with icons for a mountain, the Shiny logo, a lightbulb, a clipboard, and a rocket. The main content area has a header 'Data Review Tool' and a navigation menu with 'Home', 'Study Overview', and 'Patient Profile' (selected). The patient profile section shows 'Patient US-101-0001 - profile' with a status bar indicating 39, 41, 13, 0, and 20. Below this, a summary row lists: Study: Natevba_Data, Site: US-101, Sex: F, Age: 41, Race: NA, Ethnicity: NOT HISPANIC OR LATINO, Status: enrolled, Consent Date: 2020-05-11, and First Dose: 2020-05-18 16:18:00. The 'Vitals' tab is active, showing six line charts: Body Mass Index, Diastolic BP, Height, Systolic BP, Temperature, and Weight. Each chart has a green line with a red dot at the end, indicating a trend over time.



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