



2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Bridging the Divide: Automating CDISC Standards for Academic Research

Shirley Collie, Founder & CEO, BioInformatiCo

Speakers



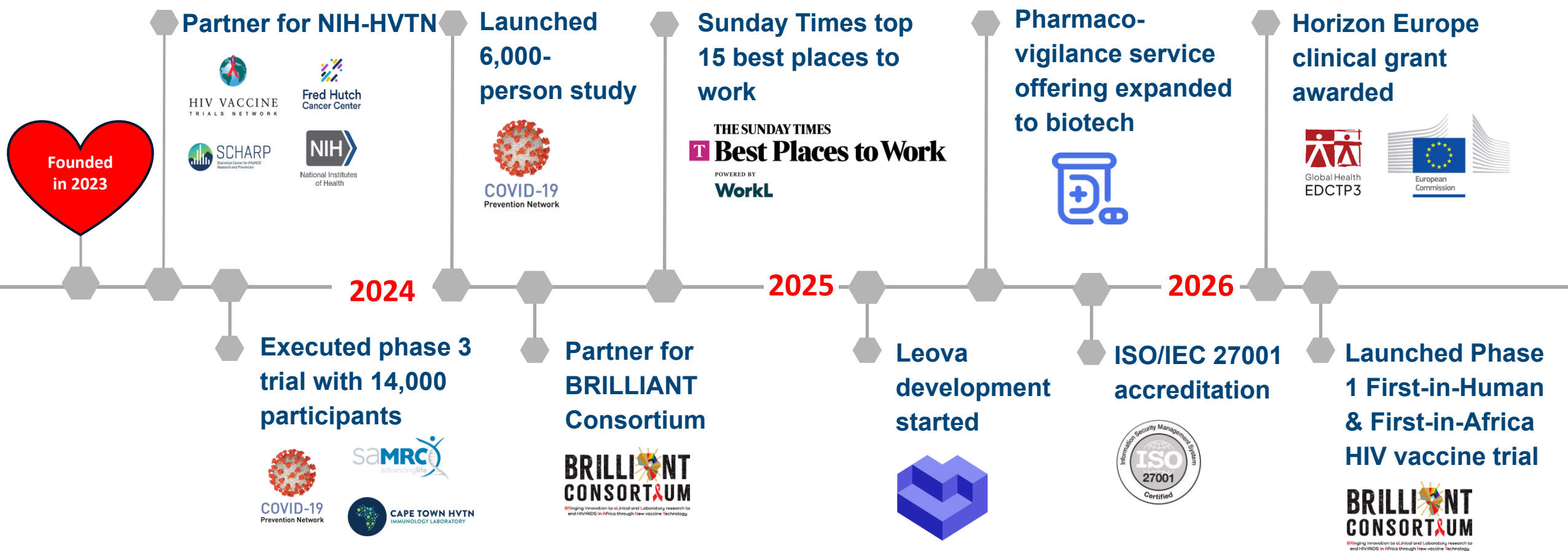
Shirley Collie
Founder and CEO
BioInformatiCo

- As the founder and CEO of BioInformatiCo, Shirley brings a wealth of experience and a deep-rooted passion for medical science to drive innovative solutions and advancements in the field. With 18 years of expertise as a healthcare actuary, Shirley held the role of Chief Health Analytics Actuary at Discovery Health, where she led the Analytic Intelligence Cluster.
- During the COVID-19 pandemic, Shirley contributed globally relevant research on behalf of Discovery Health, showcasing her commitment to addressing critical health challenges. Shirley has collaborated in academic studies with leading researchers and has published in high impact journals such as The Lancet, NEJM and BMJ. Her deep understanding of administrative healthcare data and epidemiological analytic concepts benefits BioInformatiCo's reporting to add value to study-teams.
- At BioInformatiCo, Shirley aims to advance data management and analytic services in Sub-Saharan Africa by leveraging her expertise to drive meaningful impact in the region. With a clear vision and a pragmatic approach, Shirley is focused on delivering tangible results and fostering growth in the biometrics and analytics landscape. Her leadership, coupled with her dedication to advancing healthcare, positions BioInformatiCo as a trusted partner in driving progress and innovation in the field.

Agenda

1. Introduction to BioInformatiCo
2. Academic Research Studies vs Studies on a Critical Regulatory Pathway
3. The case for CDISC implementation in academia
4. Our solution
5. Case Study & learnings
6. Discussion

Introduction to BioInformatiCo



Academic Research Studies vs Studies on a Critical Regulatory Pathway

Structural constraints

- Limited access to validated systems
- Reliance on institution-provided tools (e.g. REDCap)
- Resource constraints in evaluating and implementing fit-for-purpose platforms

Variability in operational maturity

- Differences in QMS maturity across DCCs
- Inconsistent processes across multi-study environments

Limited exposure to end-to-end regulatory workflows

- CDISC often not applied across full lifecycle (CDASH → SDTM → ADaM → Define.xml → SDRG/ADRG)
- Limited involvement in submission-grade deliverables

This is not a capability issue, it reflects differences in operating model and regulatory exposure.

The difference CDISC-ready data makes

Without CDISC-ready data

- Data rework required
- Delays in development
- Reduced asset value
- Early data excluded

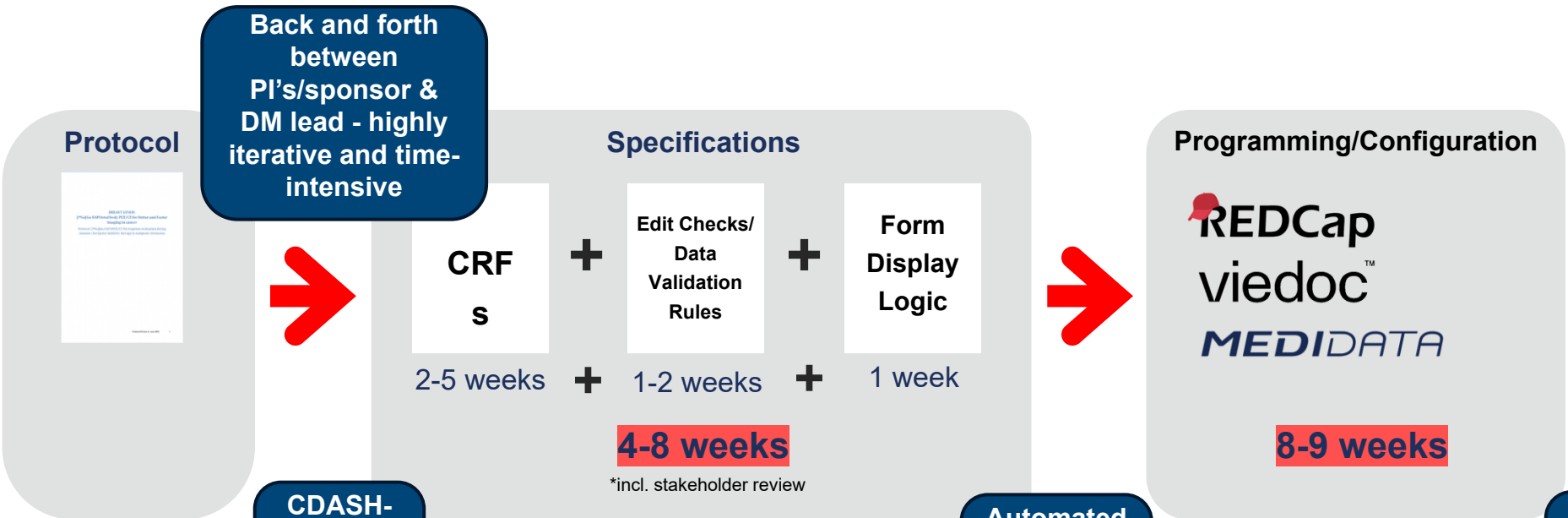
With CDISC-ready data

- Seamless transition to CRO/pharma
- Early data usable in submissions
- Faster development timelines
- Higher partner confidence

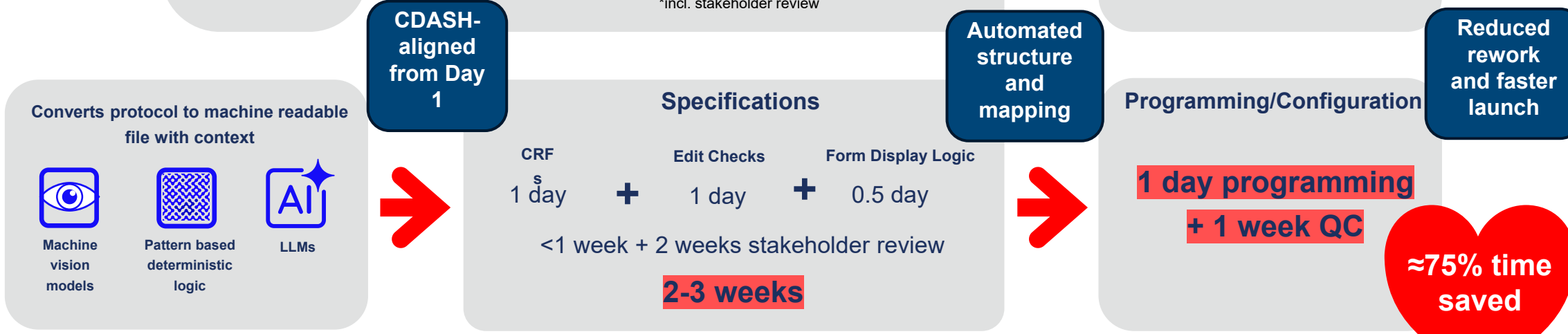
The goal is not to make every study submission-ready, but to ensure no promising study becomes submission impossible.

Leova accelerating study setup while preserving data value

Current manual workflow

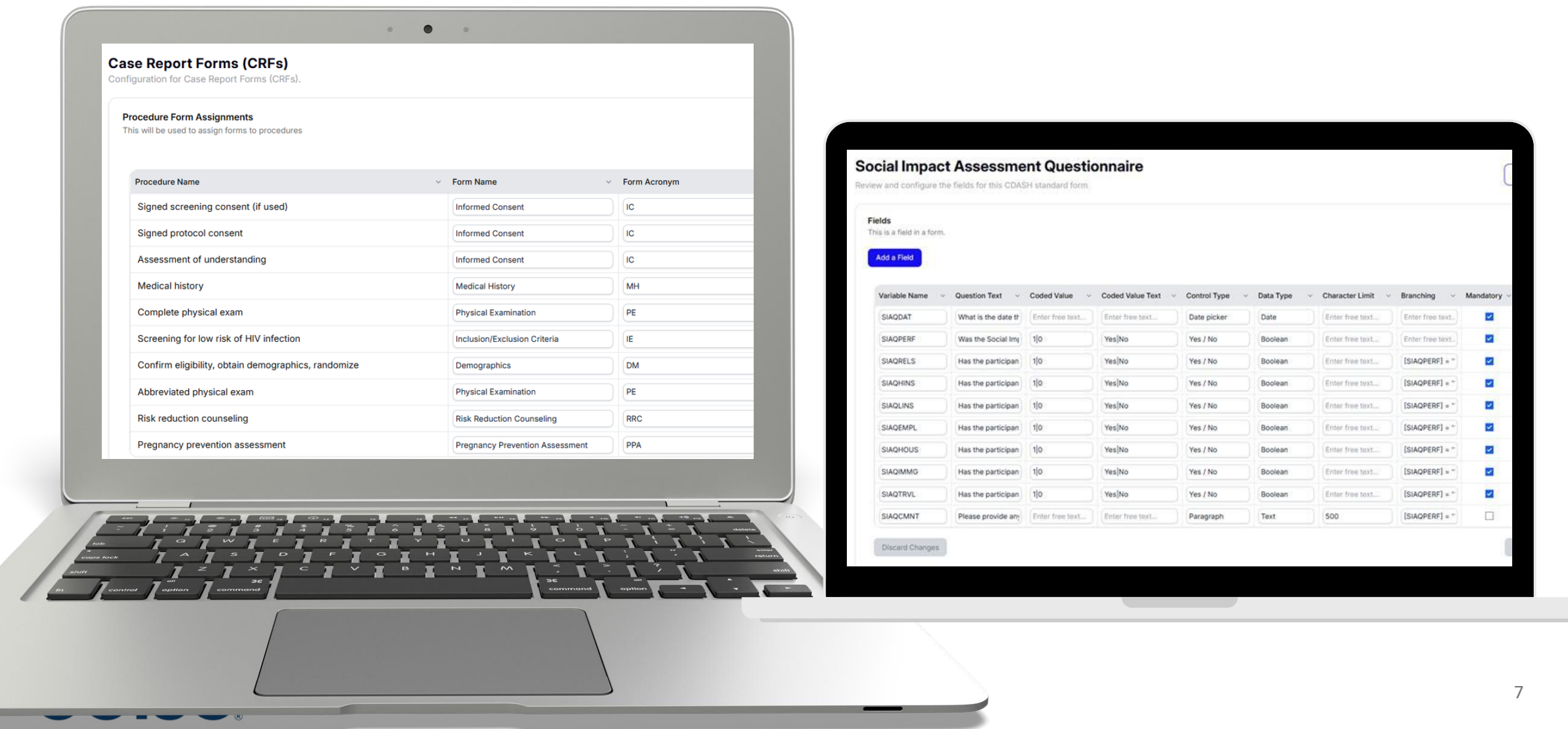


Leova



≈75% time saved

Platform in Action



We don't just implement CDASH, we operationalise it.

Embedding standards at the point of design rather than fixing data later

Case Report Forms (CRFs)

Configuration for Case Report Forms (CRFs).

Procedure Form Assignments

This will be used to assign forms to procedures

[+ Add a form](#)

Procedure Name	Form Name	Form Acronym	Source	Actions
Signed screening consent (if used)	Informed Consent	IC		☐
Signed protocol consent	Informed Consent	IC		☐
Assessment of understanding	Informed Consent	IC		☐
Medical history	Medical History	MH		☐
Complete physical exam	Physical Examination	PE		☐
Screening for low risk of HIV infection	Inclusion/Exclusion Criteria	IE		☐
Confirm eligibility, obtain demographics, randomize	Demographics	DM		☐
Abbreviated physical exam	Physical Examination	PE		☐
Risk reduction counseling	Risk Reduction Counseling	RRC		☐
Pregnancy prevention assessment	Pregnancy Prevention Assessment	PPA		☐

Protocol-driven CRF suggestion

Aligned to CDASH form library

Reduces manual interpretation

Social Impact Assessment Questionnaire

Review and configure the fields for this CDASH standard form

[Preview Form](#)

Fields

This is a field in a form.

[Add a Field](#)

Variable Name	Question Text	Coded Value	Coded Value Text	Control Type	Data Type	Character Limit	Branching	Mandatory	Actions
SIAQDAT	What is the date th	Enter free text...	Enter free text...	Date picker	Date	Enter free text...	Enter free text...	☒	
SIAQPERF	Was the Social Im	1 0	Yes No	Yes / No	Boolean	Enter free text...	Enter free text...	☒	
SIAQRELS	Has the participan	1 0	Yes No	Yes / No	Boolean	Enter free text...	[SIAQPERF] = "	☒	
SIAQHINS	Has the participan	1 0	Yes No	Yes / No	Boolean	Enter free text...	[SIAQPERF] = "	☒	
SIAQLINS	Has the participan	1 0	Yes No	Yes / No	Boolean	Enter free text...	[SIAQPERF] = "	☒	
SIAQEMPL	Has the participan	1 0	Yes No	Yes / No	Boolean	Enter free text...	[SIAQPERF] = "	☒	
SIAQHOUS	Has the participan	1 0	Yes No	Yes / No	Boolean	Enter free text...	[SIAQPERF] = "	☒	
SIAQIMMG	Has the participan	1 0	Yes No	Yes / No	Boolean	Enter free text...	[SIAQPERF] = "	☒	
SIAQTRVL	Has the participan	1 0	Yes No	Yes / No	Boolean	Enter free text...	[SIAQPERF] = "	☒	
SIAQCMNT	Please provide any	Enter free text...	Enter free text...	Paragraph	Text	500	[SIAQPERF] = "	☐	

[Discard Changes](#) [Save Changes](#)

CDASH-aligned naming

Standardised field structure

Ready for downstream mapping

Case Study: From Client Specifications to EDC ready build

CONTEXT

- First end-to-end client build using our internal study-build tool (Leova)
- Client spec stack: CRFs, edit checks, Form Display Logic, Schedule of Forms
- Three-week sprint to harden the pipeline on a real-world spec

CHALLENGES

- Real client spec exposed edge cases synthetic tests had masked
- Form Display Logic in pivoted format, new parsing capability required
- Edit checks silently dropped on import; spec artefacts shifted mid-build

INTERVENTION

- Hardened mapper: dependency ordering, cross-form references, stable OIDs
- Pivot-table reader unlocked Form Display Logic ingestion
- Reusable Claude agent for Excel → EDC JS logic conversion

IMPACT

- QC-ready database build in ~2.5 days once pipeline hardened
- Reusable tooling, not bespoke; compounds across future studies
- Weak spots explicitly documented; clear POC-to-production roadmap

Future Library Feature: Upload CRFs

Upload PDF, Word or Excel files into the Leova library

The screenshot displays two overlapping windows from the CDISC Leova library interface. The background window is the 'Pre-existing Conditions' form, and the foreground window is the 'Upload CRFs' dialog.

Upload CRFs Dialog:

- Title:** Upload CRFs
- Instructions:** Drag and drop your file here or click to browse. Only PDF, Word and Excel files are supported. You can only upload one file at a time.
- Drop Zone:** A large dashed box containing a file icon and the text "Drag and drop your CRF here" and "or click to browse files".
- Buttons:** "Browse Files" (blue text), "Download xlsx template" (blue text with a download icon), "Cancel", and "Upload" (blue button).
- Footer:** "You can upload any file or use our excel template for improved accuracy"

Pre-existing Conditions Form:

- Header:** "PROTOCOL #: XXXXX" and "Clinical Database"
- Title:** Pre-existing Conditions
- Form Fields:**
 - [mhx_vers]**: A text input field.
 - Does the participant have any pre-existing conditions?**: Radio buttons for "Yes" and "No".
 - What was the date the medication was started?**: A date input field with a placeholder "--/--/----
 - What is the pre-existing condition name?**: A text input field.
 - What was the category of the condition?**: Radio buttons for various categories: Cardiovascular, Endocrine, Respiratory, Gastrointestinal, Genitourinary, Musculoskeletal, Neurological, Endocrine/Metabolic, Blood/Lymphatic, Dermatologic, and Psychiatric.
- Version Selector:** A vertical sidebar on the right with buttons for "v1.5", "v3.0", and "v1.2".

CDASH Aligned Fields

Leova transforms the files into entities and suggests CDASH-aligned field IDs for all questions, adding coded values, data types, character limits and branching logic where needed

[← Back to CRF Selection](#)

Pre-existing Conditions

Review and configure the fields for this CDASH standard form

Fields
This is a field in a form.

Add a Field

Variable Name	Question Text	Coded Value	Coded Value Text	Control Type	Data Type	Character Limit	Branching
MHYN	Does the participant have a...	1 0	Yes No	Yes / No	Boolean	Enter free text...	Enter free text...
MHDAT	What was the date the medi...	Enter free text...	Enter free text...	Date picker	Date	Enter free text...	Enter free text...
MHTERM	What is the pre-existing me...	Enter free text...	Enter free text...	Single line text	Text	200	[MHYN] = '1'
MHCAT	What was the category of t...	1 2 3 4 5 6 7 8 9 10	Cardiovascular Endocrine /	Dropdown	Text	Enter free text...	[MHYN] = '1'
MHCATOTH	If category is Other, please...	Enter free text...	Enter free text...	Single line text	Text	200	[MHCAT] = 'Other'
MHSDAT	What was the start date of t...	Enter free text...	Enter free text...	Date picker	Date	Enter free text...	[MHYN] = '1'
MHENDAT	What was the end date of t...	Enter free text...	Enter free text...	Date picker	Date	Enter free text...	[MHYN] = '1' AND [MHONG
MHONGO	Is the pre-existing medical c...	1 0	Yes No	Yes / No	Boolean	Enter free text...	[MHYN] = '1'

Opportunities for Collaboration



Beta Tester

- Be an early adopter and influence product roadmap.
- Benefit from immediate efficiency gains free of charge.
- Joint marketing and thought leadership publication opportunities.

Thank You!



Questions?

