

Build better Medidata Rave studies, faster

TrialGrid simplifies and speeds the development of Medidata Rave studies, helping to improve the quality of study builds and manage compliance with standards.

Complying with Standards Libraries

Standards Libraries facilitate the re-use of Forms, Dictionaries and Edit Checks saving many hours of Study Build effort, but tracking compliance and permitted deviations from the standards can be time-consuming. Typically, these kinds of compliance checks are performed during the study acceptance phase, late in the process when changes are expensive and can result in timeline delays.

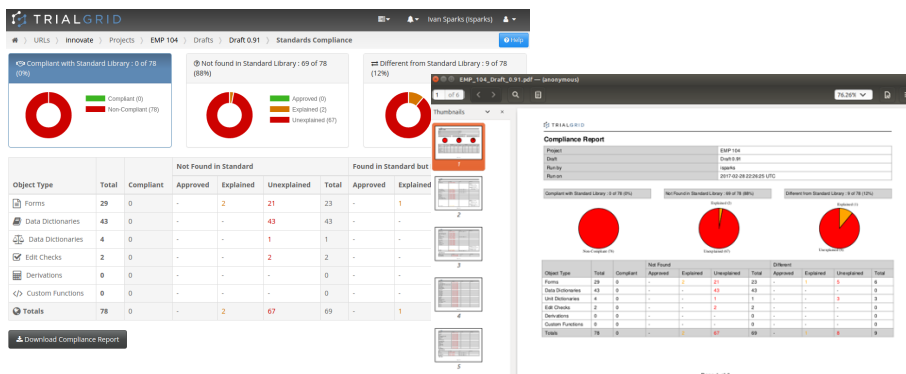
TrialGrid brings Standards Compliance checking into the Study Build process so that deviations can be identified, explained and approved or corrected earlier in the process.

Subject	✓	Fields (2)	Compare	Matched
Match to standards-innovate / DEMO_LIBRARY				
Visit	✓	Fields (5)	Compare Explanation	Denied
Modified from standards-innovate / DEMO_LIBRARY				
Disposition	✓	Fields (8)	Compare Explain	Not Explained
Modified from standards-innovate / DEMO_LIBRARY				
Drug Accountability Summary	✓	Fields (1)	Compare Explanation	Approved
Modified from standards-innovate / DEMO_LIBRARY				
Drug Accountability	Log Landscape	✓	Fields (7)	Compare Explanation Approval Requested
Modified from standards-innovate / DEMO_LIBRARY				

TrialGrid tracks the unique “fingerprint” of study design objects and matches them to one or more Standards Libraries. Deviations can be explained by the Study Builder and approved or rejected by a Standards Manager via audit trailed workflow.

Standards Compliance Reporting

Managing standards compliance and reporting on compliance metrics is made easy with the standards compliance dashboard and PDF reports which document all deviations, explanations and approvals.



Standards Compliance Dashboard Summary:

- Compliant with Standard Library: 0 of 78 (0%)
- Not Found in Standard Library: 69 of 78 (89%)
- Different from Standard Library: 9 of 78 (12%)

Compliance Report Table:

Object Type	Total	Compliant	Not Found	Different	Approved	Explained	Unexplained	Total	Approved	Explained	Unexplained	Total
Forms	29	0	2	21	23	1	5	29	1	5	23	29
Data Dictionaries	43	0	43	0	0	0	43	43	0	0	43	43
Edit Checks	2	0	2	0	0	0	2	2	0	0	2	2
Derivations	0	0	0	0	0	0	0	0	0	0	0	0
Custom Functions	0	0	0	0	0	0	0	0	0	0	0	0
Totals	78	0	67	11	23	1	43	78	1	5	72	78

About TrialGrid

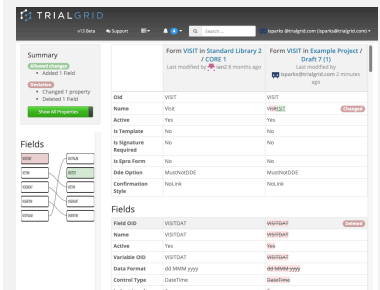
TrialGrid was founded in 2016 by Andrew Newbigging and Ian Sparks, Medidata veterans each with more than 20 years experience building software applications for clinical trials. In early 2017 Steve Heath joined as Chief Commercial Officer after a 13 year career at Medidata and over 30 years selling in the technology and life sciences space.

Medidata Rave® Focused

TrialGrid empowers Data Managers and Clinical Programmers to build better Medidata Rave studies, faster and with assured quality. Our goal is to reduce study build time by more than 50%.

Compare Differences

Color-coded comparison makes it easy to see exactly what was changed, added or removed from the Standard version

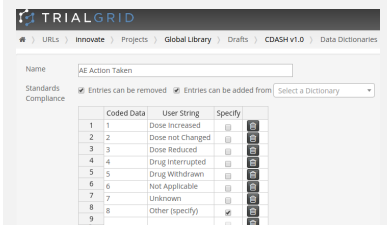


Compare Differences Interface:

- Left Panel: Summary of changes (Added, Changed, Deleted).
- Right Panel: Comparison table with columns for Field ID, Name, Active, Is Required, Is Signature Required, Is Data Form, Data Option, Confirmation, and Date.
- Fields List: A list of fields with their IDs and names, color-coded to show differences.

Permitted Changes

Some changes to standard objects are expected such as the addition of entries to a Dictionary from a Controlled Terminology. TrialGrid allows a Library Manager to define rules for permitted changes.



Permitted Changes Configuration Table:

Coded Data	User String	Specify
1	Dose Increased	<input type="checkbox"/>
2	Dose not Changed	<input type="checkbox"/>
3	Dose Reduced	<input type="checkbox"/>
4	Drug Interrupted	<input type="checkbox"/>
5	Drug Withdrawn	<input type="checkbox"/>
6	Not Applicable	<input type="checkbox"/>
7	Unknown	<input type="checkbox"/>
8	Other (specify)	<input type="checkbox"/>
9		<input type="checkbox"/>

Contact

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