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Interactive Data Access

Exploring the Possibilities With TrialMaster Data Grids

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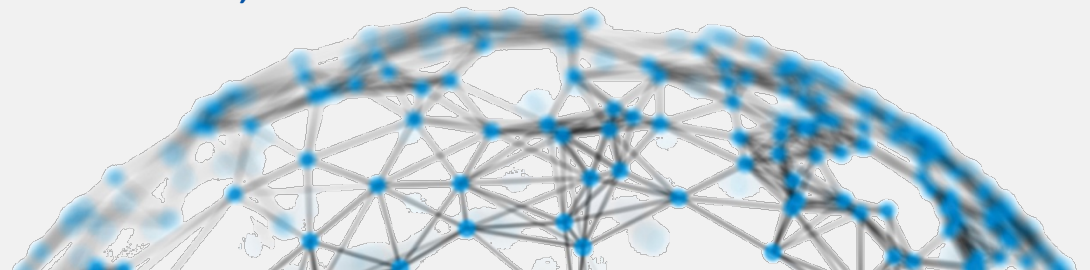
The EDC of choice for over
5,000 clinical trials around the world



An anecdotal example from last week

- CRO organized an Ad-Hoc Reporting demo for customer
- Showed process of creating reports and the types of output possible in ad-hoc
- Customer didn’t need flexibility to self-create reports
- Customer didn’t need graphical representation of data
- Discussed creating a custom export of ‘just’ the data they needed
- Ideally wanted to run the export themselves
- Isolated customer requirement to needing a fixed report (listing) in MS Excel that they could trigger as required
- Ideal solution then identified as a TrialMaster Data Grid

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Business Challenges/Need

- EDC Users find it helpful to access summarized clinical data that:
  - Is accessed all in one place – no skipping through multiple eCRFs
  - Is *just* the eCRF questions required for review
  - Can contain calculated data
  - Is *restricted* to desired content and can be further sorted/filtered by the user
  - Can be executed at the patient, site or trial level
  - Can link back to the associated eCRFs
  - Can be exported quickly for utilization outside of TrialMaster
  - Can be exported into custom PDF forms

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Solution Overview – What are Data Grids ?

- Data Grids are tabular views of data collected within a trial
- Any number of Data Grids can be defined for a trial and the content is configurable when they are defined
- A user can select the whole trial, a site or a subject and run a Data Grid to view the content
- Data Grids can also be mapped to PDF form documents to export the content in a pre-defined format.

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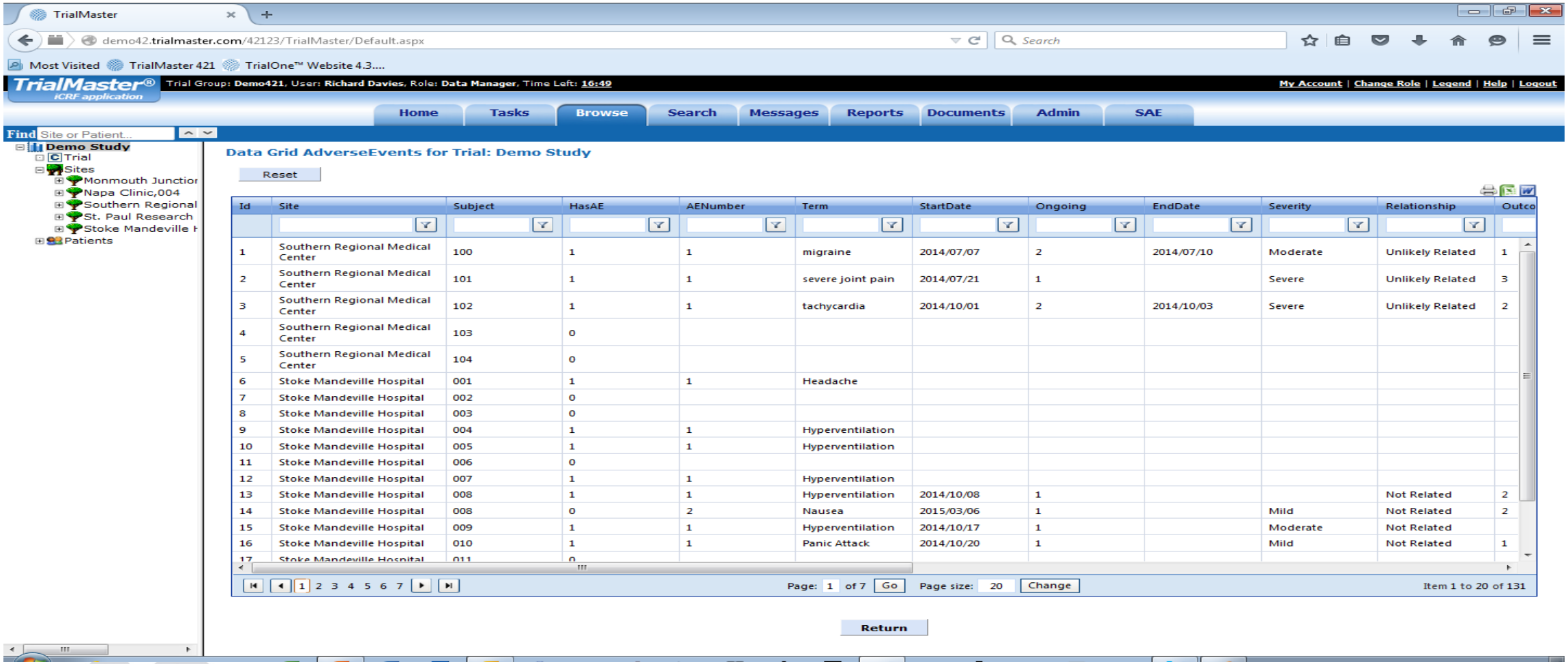
Solution Overview - Example – All Trial Adverse Events



Id	Site	Subject	HasAE	AENumber	Term	StartDate	Ongoing	EndDate	Severity	Relationship	Outco
1	Southern Regional Medical Center	100	1	1	migraine	2014/07/07	2	2014/07/10	Moderate	Unlikely Related	1
2	Southern Regional Medical Center	101	1	1	severe joint pain	2014/07/21	1		Severe	Unlikely Related	3
3	Southern Regional Medical Center	102	1	1	tachycardia	2014/10/01	2	2014/10/03	Severe	Unlikely Related	2
4	Southern Regional Medical Center	103	0								
5	Southern Regional Medical Center	104	0								
6	Stoke Mandeville Hospital	001	1	1	Headache						
7	Stoke Mandeville Hospital	002	0								
8	Stoke Mandeville Hospital	003	0								
9	Stoke Mandeville Hospital	004	1	1	Hyperventilation						
10	Stoke Mandeville Hospital	005	1	1	Hyperventilation						
11	Stoke Mandeville Hospital	006	0								
12	Stoke Mandeville Hospital	007	1	1	Hyperventilation						
13	Stoke Mandeville Hospital	008	1	1	Hyperventilation	2014/10/08	1			Not Related	2
14	Stoke Mandeville Hospital	008	0	2	Nausea	2015/03/06	1		Mild	Not Related	2
15	Stoke Mandeville Hospital	009	1	1	Hyperventilation	2014/10/17	1		Moderate	Not Related	
16	Stoke Mandeville Hospital	010	1	1	Panic Attack	2014/10/20	1		Mild	Not Related	1
17	Stoke Mandeville Hospital	011	0								

1 2 3 4 5 6 7 Page: 1 of 7 Go Page size: 20 Change Item 1 to 20 of 131

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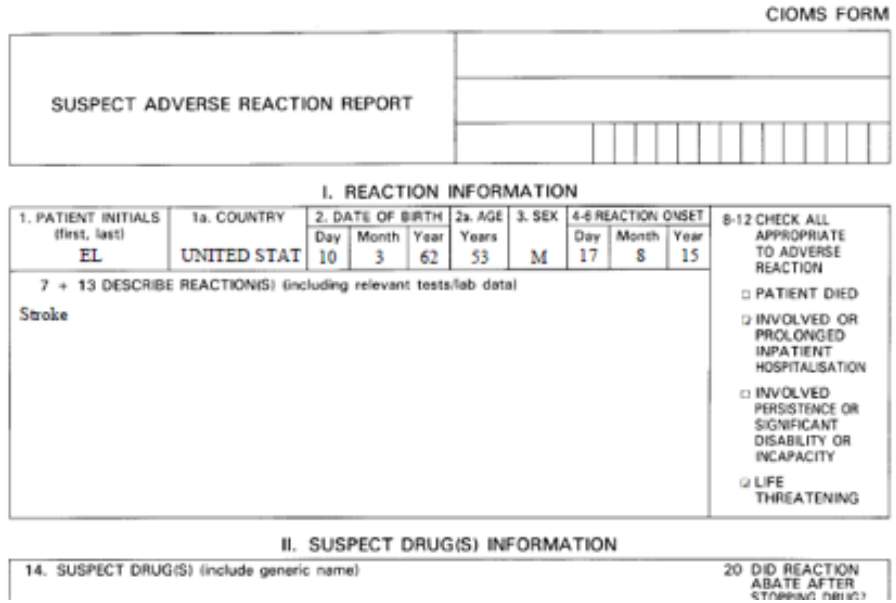
Solution Overview - Data Grid export to PDF

- Data Grids have the option to export content into PDF forms
  - Allows records included in a data grid to be output into a PDF document such as a Monitoring Report or Regulatory document such as a CIOMS-I Adverse Event Report
  - Data is then displayed in a more readable format than a traditional data listing



CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
EL	UNITED STAT	10	3	62	53	M	17	8	15	☐ PATIENT DIED

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Stroke

☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION

☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY

☑ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) 20 DID REACTION ABATE AFTER

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How do Data Grids compare to ad-hoc reporting ?

- Ad-hoc reports also provide custom views of clinical data
- However:
  - Ad-hoc reporting is typically a CRO/Sponsor tool and not granted to Sites. Data Grids easily accessible to all.
  - Data Grids cannot be configured on the fly, they're built in TrialBuilder and deployed with the trial or any MSC.
  - Data Grids are tabular, while ad-hoc reports can be graphical

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Who Benefits & How

- Target Users:
  - Investigators who may be interested in key endpoint data
  - Monitors who may be interested in dropouts or protocol deviations
  - Data Managers who may be interested in reconciling data across eCRFs
  - Medical Reviewers interested in out of range lab data
  - Pharmacovigilance interest in AE related data

- The use cases are varied and the value of data grids applicable to multiple user types.

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Value Summary

- Applicable to many user types
- Quick to access
- Allows users to have targeted data review
- Flexible content to support varied use cases
- Streamlined user experience for data review
- Easily output data into sponsor-defined PDF documents

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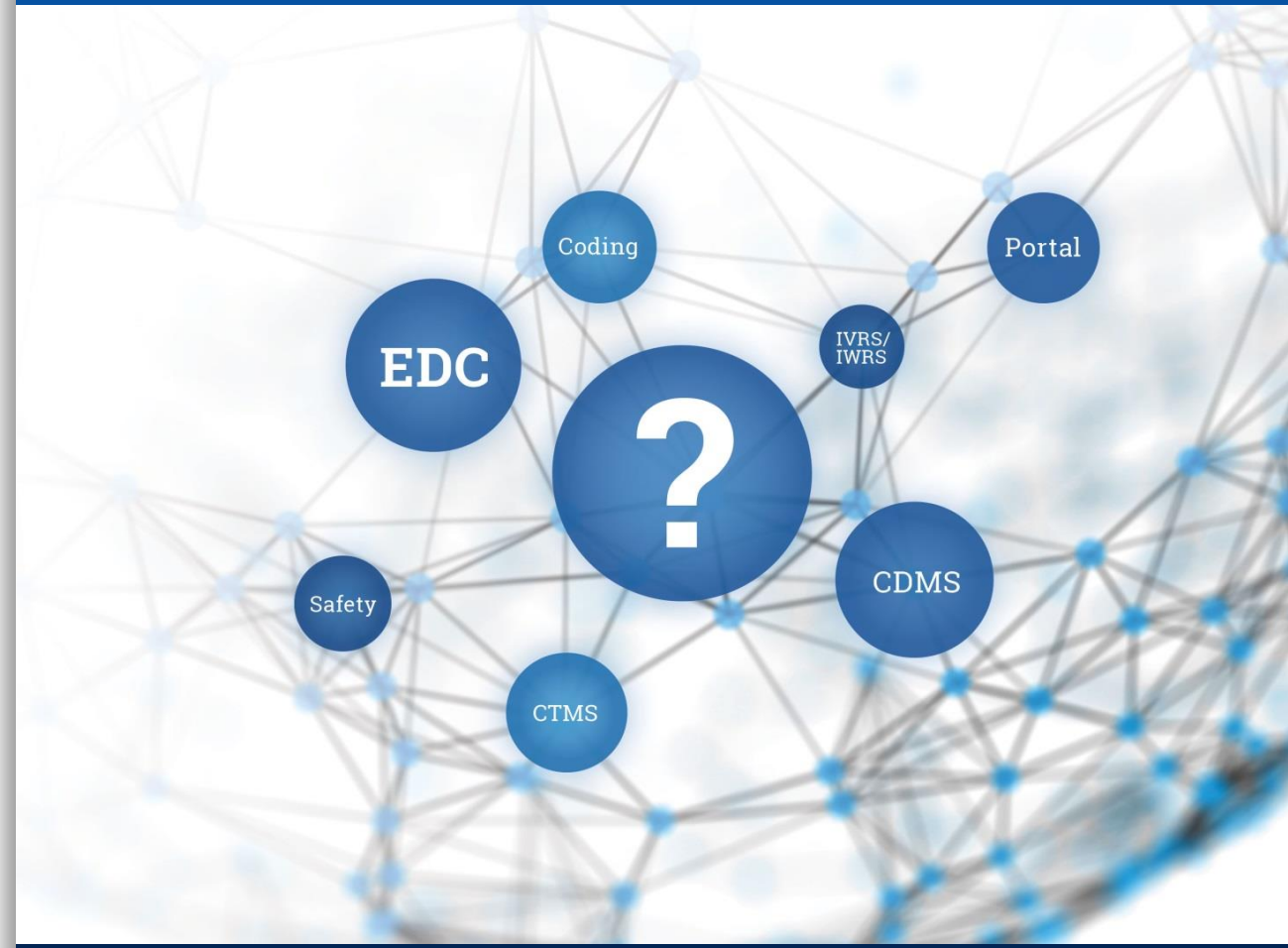

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