

Visibility of Data: Enabling Management & Direction From A Distance

Graham Downing

Vice President, Global Data,
Statistics & Technology

WORLDWIDE CLINICAL TRIALS



14th DIA Annual Workshop in
Japan For Clinical Data
Management
27-28 January
Tower Hall Funabori, Tokyo

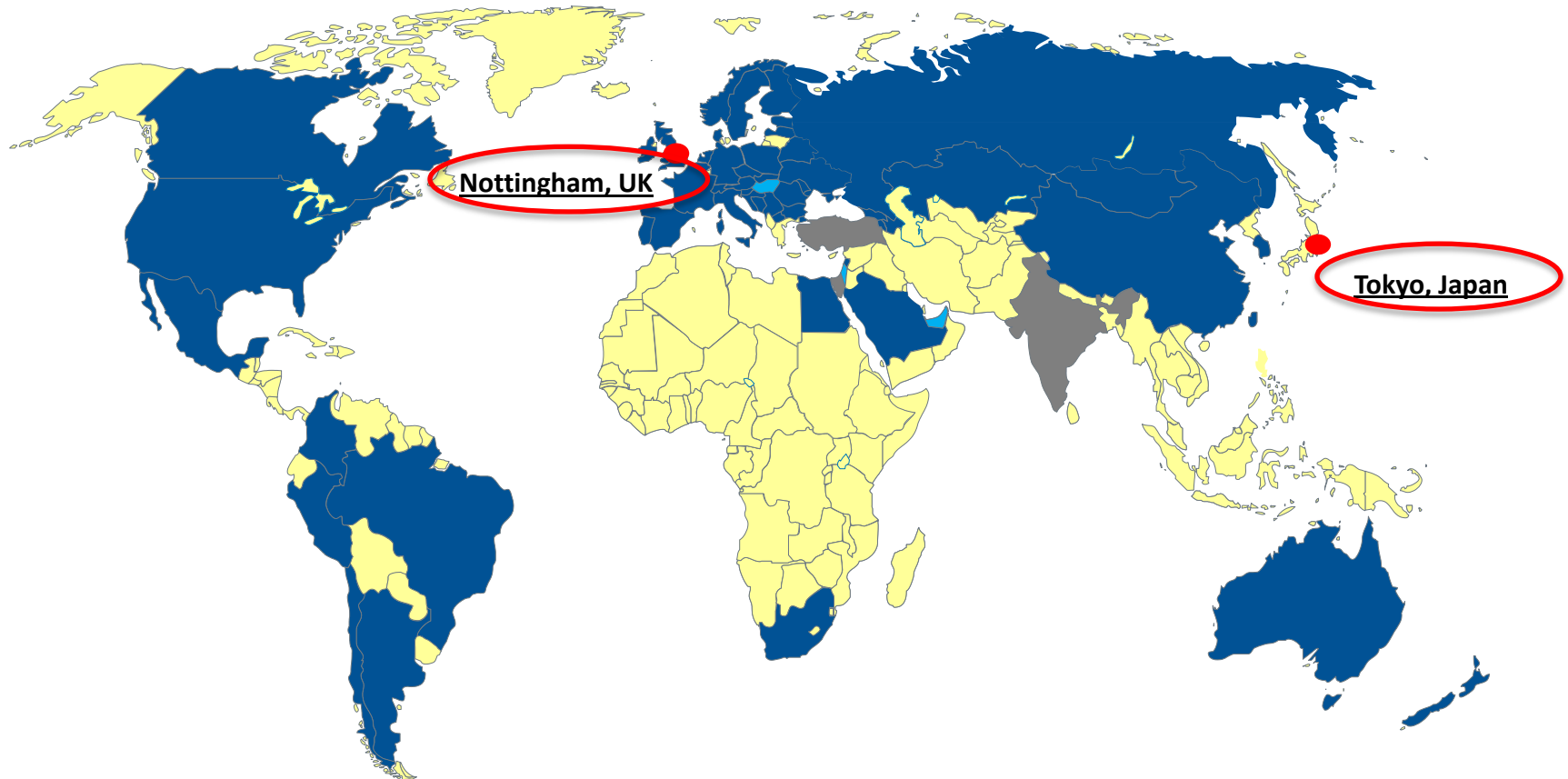
- What is going on with my trial?
- Where can I get information?
- How can this work from so far away?



- CDMS Clinical Data Management System
- CRFs Case Report Forms
- CTMS Clinical Trial Management System
- EDC Electronic Data Capture
- ePRO Electronic Patient Reported Outcomes
- ERP Enterprise Resource Planning
- IVRS Interactive Voice Response System
- IWRS Interactive Web Response System
- KPIs Key Performance Indicators
- SAEs Serious Adverse Events



Where Am I?



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What Are We Doing?

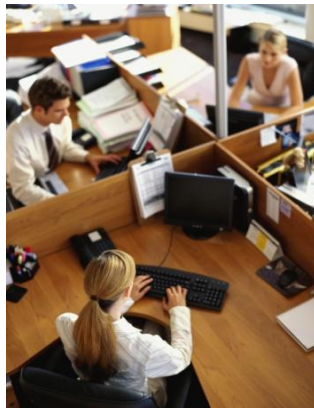
Tokyo, Japan



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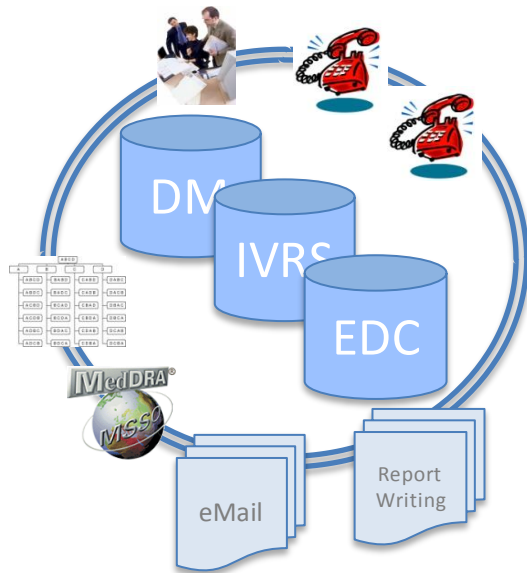
What is everyone else doing?



Nottingham, UK

CLINICAL DATA ENTRY		User: Cordelia Bernai-Zakrajsek	
Site:		Change Case	Help
Case: Patient initials: ...		Summary	No Queries
Debug			
Change Case			
Open case Specify another case for data entry			
Site Number	<input type="text"/>	(nnnn)	
Patient Number	<input type="text"/>	(5nnn)	
Notes:			
<ol style="list-style-type: none"> After entry of both Site Number and Patient Number you may click on either the Open Case tab to the left, or the Summary link, to open the chosen Case. You may click on a header graphic button without this form being submitted. 			

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CLINICAL DATA ENTRY		User: Katie Jarvis	
Site: [3305] University Hospital		Change Case	Help
Case: 0001 Patient initials: EIM		Summary	Queries
Prev. Med.		ECG	Lab Results
Demography		Cardio Hist	Non Card His
Baseline		Incl Excl	
Visits		Phys Exam	
Baseline: Demographics			
Date of birth	7 Feb 1924		
Gender	<input checked="" type="radio"/> Male <input type="radio"/> Female		
Ethnic origin	<input type="radio"/> Caucasian <input type="radio"/> Afro-caribbean <input type="radio"/> Asian <input type="radio"/> Other + <input checked="" type="radio"/> Specify mixed race		
Smoking history	<input type="radio"/> Current <input type="radio"/> Past <input type="radio"/> Never +		
Baseline: Onset of qualifying event			
Date	1 Nov 2000		
Time	1:00		
<input type="button" value="Reset"/>		<input type="button" value="Save"/>	
		<input type="button" value="Check"/>	



Worldwide: What is Going On?



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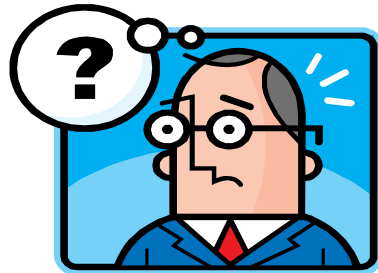
Data Collection

- CRF
- EDC
- IVRS
- IWRS
- ePRO
- Laboratory Data
- Drug Safety Information
- Tracking Systems
- Monitoring Visit Reports
- Study milestones & payment points
- ERP

Data Storage

- CDMS
- Randomisation
- Drug Supply Management
- Safety Database
- CTMS
- Portfolio Repository
- ERP

- Project Manager
 - Team
 - Line Managers
 - Sponsors and Investors
 - Investigators and Sites
 - Collaborators
 - Regulators
- Ask, ask, ask
 - Micro manage
 - Interrupt
 - Email
 - Overnight messages
 - Late night and early morning calls
 - Run around
 - Have someone run reports
 - Print
 - Ask, ask, ask



Are There Better Ways?

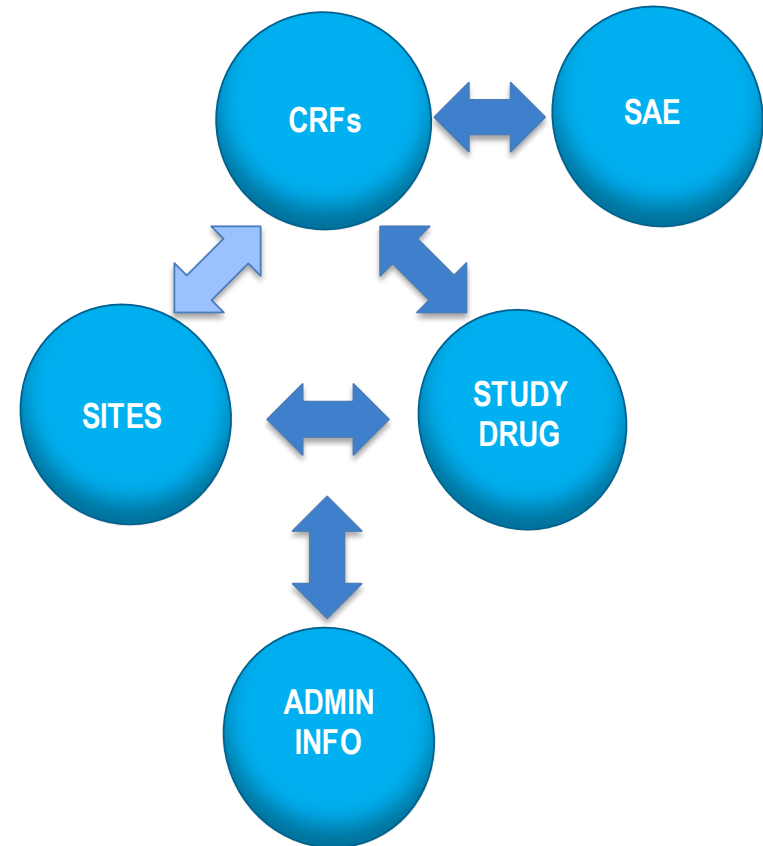
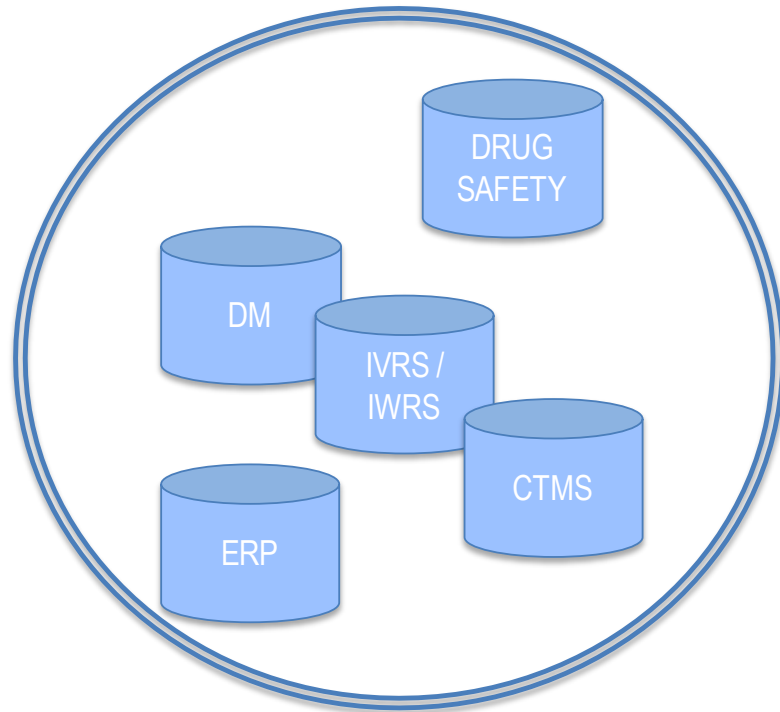


**Yes
let's walk through this**

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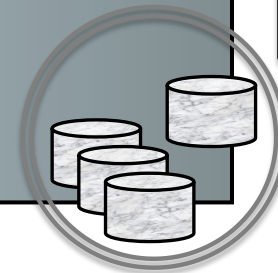


- Where is your data?



Consider the scenario:

- ➔ CTMS collects site detail during start-up, enables site activities in other systems
- ➔ IVRS collects enrolment and randomisation data, enables Data Management system to start
- ➔ IVRS triggers drug management and supply ordering
- ➔ DM system uses CTMS and IVRS data and enables EDC entry of CRF data
- ➔ Adverse Events feed across to safety database for reconciliation and regulatory processing
- ➔ Combined information available to users



So, what is available?



- Integrated tracking from feasibility to study start-up, through enrolment and patient management to final report
- Study data, tracking information and ongoing study metrics – analyse plan vs. actual progress
 - Enrolment
 - Patient visits achieved
 - Data Entered
 - Query status relative to study milestones
 - “Top 10” queries vs. data - feedback loop to monitors and sites
 - Real study data (dirty)
 - Risk management
- Portfolio data
 - Business view
 - Metrics
 - KPIs
 - Risk management

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WCT Clinical Trials Information - Mozilla Firefox

Worldwide Clinical Trials UK Limited (GB) https://www.wctrials.net/nodes.html

Project Dash

Home > Sponsor Reports

Screening / Recruitment Status Generated: 04 Jan 2011 04:07 AM

→ Site Information → Patient Information

Site Information							
	Target # of sites	# Sites activated	# Sites with drug registered (*)	# Sites screening	# Sites recruiting	# Sites initiated > 6 wks, no pts	# Sites that recruited at least 1 pt in last 14 days
Total Overall	979	1040	1040	800	1036	4	0
North America	355	324	324	322	322	2	0
Canada	50	55	55	54	53	2	0
Puerto Rico	5	8	8	8	8	0	0
USA	300	261	261	260	261	0	0
Western EU	421	449	449	285	448	1	0
Austria	15	17	17	17	17	0	0
Belgium	20	32	32	0	32	0	0
Denmark	10	19	19	7	19	0	0
Finland	20	7	7	0	7	0	0
France	25	25	25	2	25	0	0
Germany	40	42	42	40	42	0	0
Israel	18	27	27	0	26	1	0
Italy	60	54	54	54	54	0	0
Netherlands	35	36	36	13	36	0	0
Norway	20	18	18	1	18	0	0

Done www.wctrials.net

- Web interface
- Ease of Access
- Export reports
- Download data
- Complete transparency
- Progress
- Target vs Actual



WCT Clinical Trials Information - Mozilla Firefox
 File Edit View History Bookmarks Tools Help
 Worldwide Clinical Trials UK Limited (GB) https://www.wctrials.net/nodes.html
 Share Browser WebEx*

Screening / Recruitment Status

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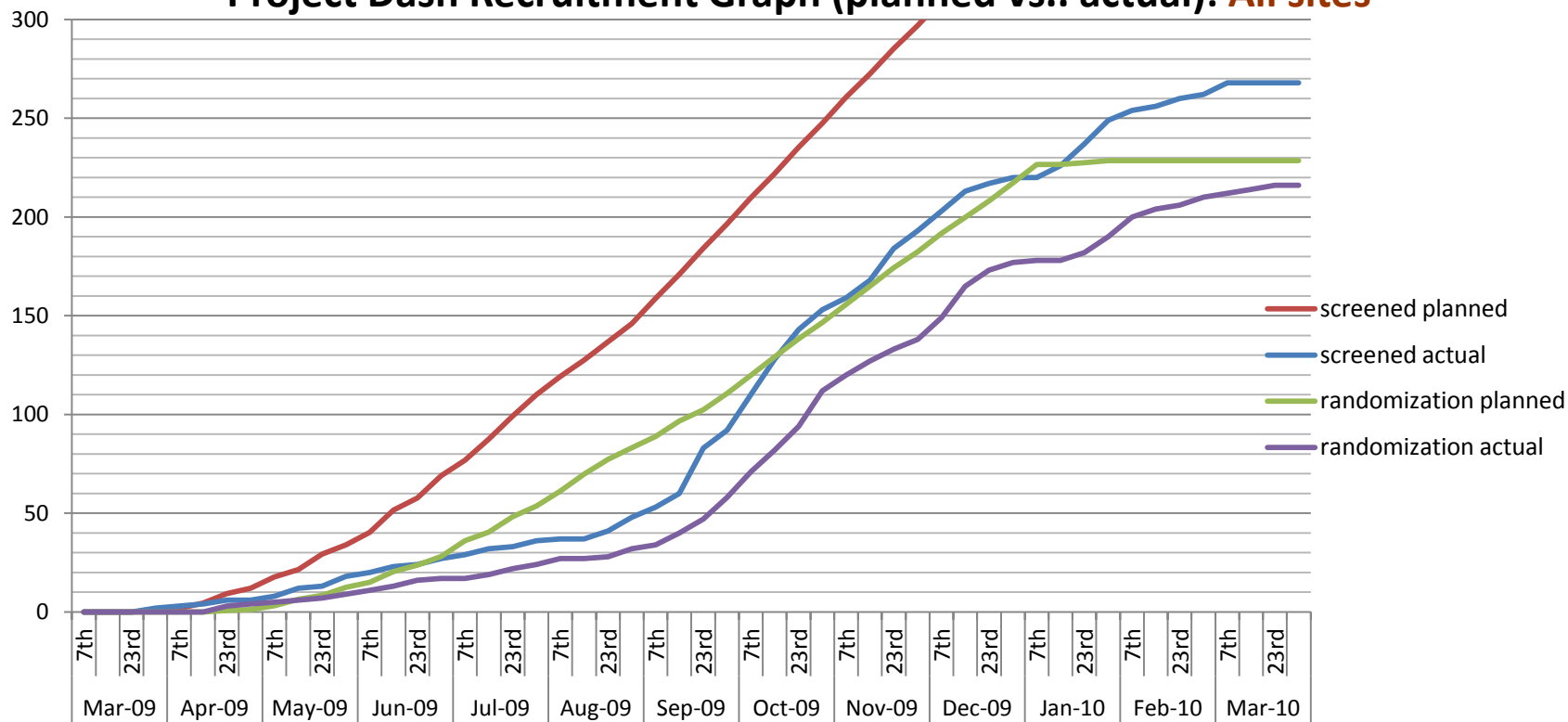
→ Site Information → Patient Information

Site Information	CTMS		IVRS	EDC		CTMS/EDC	EDC
	Target # of sites	# Sites activated	# Sites with drug registered (*)	# Sites screening	# Sites recruiting	# Sites initiated > 6 wks, no pts	# Sites that recruited at least 1 pt in last 14 days
Total Overall	979	1040	1040	800	1036	4	0
North America	355	324	324	322	322	2	0
<u>Canada</u>	50	55	55	54	53	2	0
<u>United States</u>	305	269	269	268	269	0	0
<u>Europe</u>	250	229	229	222	229	2	0
<u>Asia</u>	174	156	156	156	156	0	0
<u>Africa</u>	100	90	90	90	90	0	0
<u>Oceania</u>	50	46	46	46	46	0	0
<u>Other</u>	100	94	94	94	94	0	0
<u>Denmark</u>	10	19	19	7	19	0	0
<u>Finland</u>	20	7	7	0	7	0	0
<u>France</u>	25	25	25	2	25	0	0
<u>Germany</u>	40	42	42	40	42	0	0
<u>Israel</u>	18	27	27	0	26	1	0
<u>Italy</u>	60	54	54	54	54	0	0
<u>Netherlands</u>	35	36	36	13	36	0	0
<u>Norway</u>	20	18	18	1	18	0	0

Done www.wctrials.net



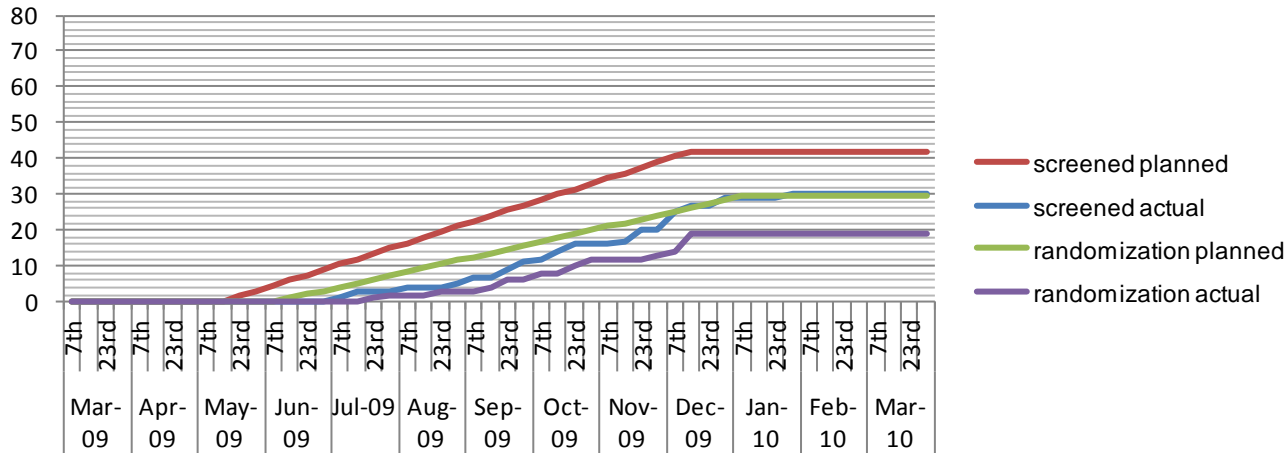
Project Dash Recruitment Graph (planned vs.. actual): All sites



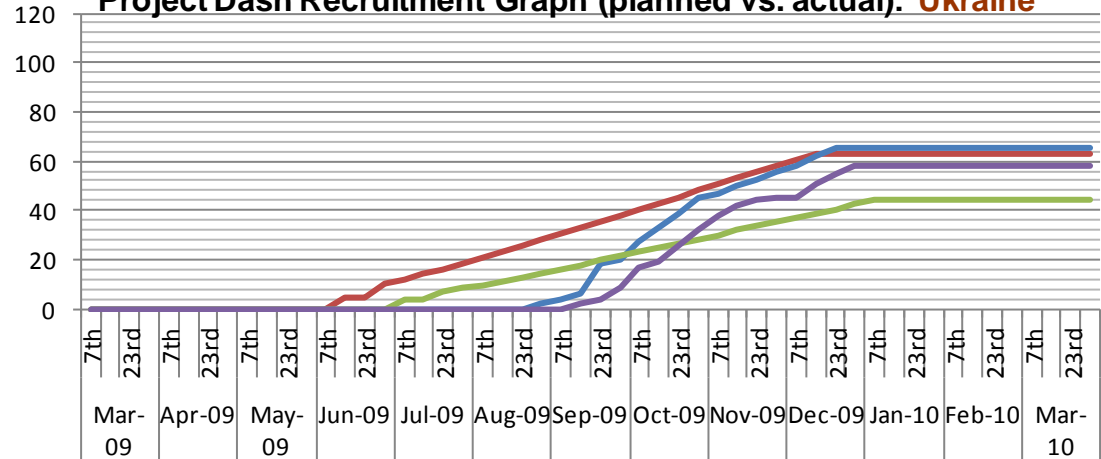
Recruitment Vs Plan – By Country



Project Dash Recruitment Graph (planned vs. actual): Serbia



Project Dash Recruitment Graph (planned vs. actual): Ukraine



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Recruitment vs. CRFs vs. Queries

Queries relative to recruitment: By Country						
Country	Tracking/CTMS/EDC			Tracking	EDC	
	First Patient	Latest Patient	Patients Recruited	CRFs in-house	Queries issued	Queries Outstanding
<u>Austria</u>	05-May-2010	04-Jan-2011	12	8	67	45
<u>Belgium</u>	11-May-2010	28-Dec-2010	32	22	183	73
<u>Canada</u>	03-Apr-2010	03-Jan-2011	55	43	425	168
<u>Denmark</u>	08-May-2010	04-Jan-2011	23	20	175	65
<u>Estonia</u>	23-Jul-2010	30-Dec-2010	16	9	85	35
<u>France</u>	30-May-2010	14-Dec-2010	56	23	245	98
<u>Germany</u>	01-Jun-2010	17-Dec-2010	43	32	255	101
<u>Hungary</u>	03-May-2010	04-Jan-2011	34	26	221	168
<u>Italy</u>	05-Aug-2010	19-Dec-2010	3	2	23	13
<u>Japan</u>	01-May-2010	06-Jan-2011	47	38	380	151



Queries relative to recruitment: Austria

Site number	First Patient	Latest Patient	Patients Recruited	CRFs in-house	Queries issued	Queries Outstanding
<u>3401</u>	05-May-2010	03-Jan-2011	2	1	8	0
<u>3402</u>	08-Nov-2010	04-Jan-2011	2	1	7	4
<u>3403</u>	17-Oct-2010	19-Aug-2010	2	2	18	18
<u>3404</u>	20-Aug-2010	01-Jan-2011	3	2	12	5
<u>3405</u>	23-Sep-2010	23-Sep-2010	1	1	10	6
<u>3406</u>	05-Jul-2010	19-Dec-2010	2	1	12	12



What have we achieved?



Reactive

- Ask, ask, ask
- Micro manage
- Interrupt
- Email
- Overnight messages
- Late night and early morning calls
- Run around
- Have someone run reports
- Print
- Ask, ask, ask

Proactive

- Notification and alerts
- Monitor progress
- Leave others to there work
- Email
- Shared areas
- Planned discussion
- Sit down
- Read
- See online
- Look, look, look



- Data is “live” – we can manage in real time
- I can see this from anywhere (from Tokyo to Nottingham and beyond)
- Study data will be in the process of being cleaned
 - So bear with us while we clean it
- Data is only as good as what is entered
 - So set mission of the entry to be up to date (but expect some lag)
 - Be aware that each entry integrates with other data
- ❖ Proactively manage with data, not by micro-managing people

- 3rd party EDC system hosted externally
- ePRO
- Project Registry
- IVRS / IWRS
- Drug Safety database in another system

Can we still manage by
integrated information?

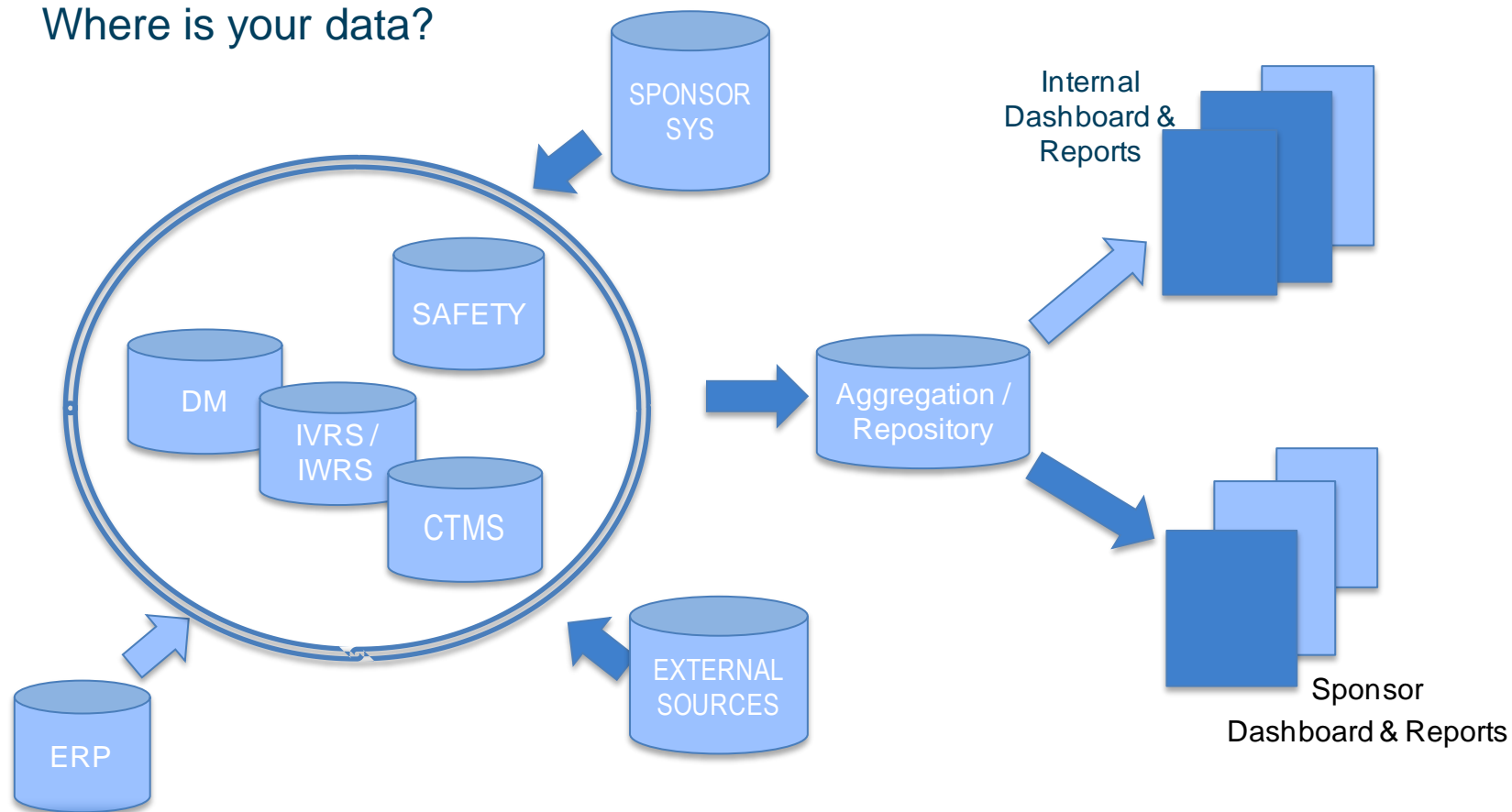
Yes!!

- Master Data Administration
 - Understand where the master record is created and managed
 - Maintain data naming conventions
 - What do you call “site”?
- Extract, Transform and Load
- Data aggregation
- Data repository
- Dashboard and reports



Question 2

- Where is your data?



What have we done?

- Moved the data from far away to be right at your fingertips
- Enabled you to manage from a distance
- Set you free to direct from a distance and have trust in what we deliver



Graham.Downing@wwctrials.com

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