WITH STANDARDS – UNLOCK THE POWER OF DATA

MerAtive



Transcelerate DDF – SDR-RI MVS Streamlining Protocol to Study Design

Jennifer Duff, General Manager, Clinical Development Solutions Mark Laney, Clinical Development Sales Engineering & Product Partnership Lead



Meet the Speakers



Jennifer Duff

Title: General Manager, Clinical Development Solutions

Organization: Merative

Jennifer has over 24 years of experience in the Life Sciences industry with specialization in enabling and scaling industry-leading services and technology solutions for pharma, med device and biotech clients. In her role as General Manager, Clinical Development Solutions, she is responsible for harnessing the power of their unified clinical data management and data acquisition technology along with the skills of the consulting & services team members to solve complex challenges for their customers in the Life Sciences industry. Merative solutions empower their customers to take control in every stage and their solution is designed to help accelerate trial outcomes with confidence, to help put you at the center of health.

Mark Laney

Title: Clinical Development Sales Engineering & Product Partnership Lead

Organization: Merative

Mark has over 20 years of experience with software in the Life Sciences industry focused on delivering the right solutions for customers. As the Sales Engineering and Product Partnerships Leader for Merative Clinical Development, he is tasked with solving customer challenges using the breadth of functionality and flexibility of Merative's unified clinical data management solution while facilitating partnerships with complimentary industry leading vendors to offer customers a robust technology solution for their clinical needs. Prior to joining Merative, Mark held roles in training, implementations, client success, and technical sales as part of the Merge Healthcare eClinical team that launched and scaled the platform now known as Clinical Development.



Disclaimer and Disclosures

 The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.

The information contained in this publication is provided for informational purposes only. While efforts were made to verify the completeness and accuracy of the information contained in this publication, it is provided AS IS without warranty of any kind, express or implied. In addition, this information is based on Merative's current product plans and strategy, which are subject to change by Merative without notice. Merative shall not be responsible for any damages arising out of the use of, or otherwise related to, this publication or any other materials. Nothing contained in this publication is intended to, nor shall have the effect of, creating any warranties or representations from Merative or its suppliers or licensors, or altering the terms and conditions of the applicable license agreement governing the use of Merative products.

Product release dates, availability and/or capabilities referenced in this presentation may change at any time at Merative's sole discretion, and are not intended to be a commitment to future product or feature availability in any way. Not all Merative products are available in all jurisdictions in which Merative operates. Nothing contained in these materials is intended to, nor shall have the effect of, stating or implying that any activities undertaken by you will result in any specific performance results, and an individual user may achieve results different than any stated here.

Merative's statements regarding its plans, directions and intent are subject to change or withdrawal without notice at Merative's sole discretion. Information regarding potential future products is intended to outline our general product direction and it should not be relied on in making a purchasing decision. The information mentioned regarding potential future products is not a commitment, promise, or legal obligation to deliver any material, code or functionality. Information about potential future products may not be incorporated into any contract. The development, release, and timing of any future features or functionality described for our products remains at our sole discretion.

Any customer examples described are presented as illustrations of how those customers have used Merative products and the results they may have achieved. Actual environmental costs and performance characteristics may vary by customer.

Merative, the Merative logo, and merative.com are trademarks of Merative, registered in many jurisdictions worldwide. Other product and service names might be trademarks of Merative or other companies.



Agenda

- 1. Defining the Transcelerate DDF SDR RI MVS project
- 2. Our experience
- 3. Benefits and future potential

Transcelerate DDF – SDR-RI MVS

Digital Data Flow (DDF) Study Definitions Repository (SDR) Reference Implementation (RI) Minimum Viable Solution (MVS)

Transcelerate **Digital Data Flow** Initiative

What is the DDF Initiative?

"The Digital Data Flow (DDF) initiative aims to modernize clinical trials by enabling a digital workflow to allow for automated creation of study assets and configuration of study systems to support clinical trial execution. This initiative will establish a foundation for a future state of automated and dynamic readiness that can transform the drug development process."

What is the SDR Project?

"The initial objective of DDF is to automate and expedite the study start-up process by revolutionizing how data flows."

What is the RI Phase?

"Transcelerate will develop an open-source, vendor agnostic, SDR reference implementation (SDR RI). The SDR reference implementation will enable the format of information from a digitized protocol and other sources to be standardized and thus allow the information to be passed to systems that are used for study execution and data collection, and reused throughout the clinical development lifecycle."

Source: Direct Data Flow Overview, Transcelerate Biopharma Inc.



The role of CDISC in DDF

"To create a consistent, comprehensive, and structured representation of a study definition as described in text in clinical trial protocols, **CDISC data standards will need to be augmented and a new standard defined.** To this end, the USDM will be created, and study definitions in the SDR will conform to this data standard."

"The USDM will consider existing standards ... The new concept-based standards aim to link the different standards by providing additional semantics to enable **metadata-driven automation**."

Source: Direct Data Flow Overview, Transcelerate Biopharma Inc.





The DDF SDR-RI vision

How API-Enabled Definition Repository & Integration will work?



Source: Direct Data Flow Overview, Transcelerate Biopharma Inc.

cdisc



Vision for Data Flow from SDR to downstream systems



Source: Architectural Review Session, Transcelerate Biopharma Inc.

cdisc

Our expectations coming into the MVS project

We got this! – by the end:

- · We will demonstrate flow from design into Merative Clinical Development
- We will demonstrate measurable efficiency & speed
- We can leverage existing API capability within our system = low dev investment

The Future will be Bright

- Minimal study build times
 - Simplify processes
 - Remove silos
 - Remove manual work
 - Reduce transformation
- · Significantly reduce need to create study-level requirements





Our Experience

•

Competitors working as colleagues

Collaboration:

- Ultimately, we all want the same thing
 - To make it easier to get treatments to patients
- Sharing lessons learned
 - Technical and Non-Technical
- Constructive and respectful disagreements
 - USDM v ODM

Feedback and Change:

- As a group, we aligned on changes
 - Regular meetings as a group
 - In-person workshop
- Feedback implemented / considered

Implementation:

- Building POCs
 - "Spare" time
 - Collaborating up/down stream
 - Demonstrations



The Process

Initiation:

- Project kick-off
- · Team build up
- Credentials
- Regular meetings
- Development

Connection Showcase:

- Upstream
 - Study Design
- Downstream
 - <u>EDC</u>
- Collaboration

Connect-a-thon:

- Open to the industry
 - Data Interoperability
 - UI/UX
 - Analytics/Reporting
 - Supplemental Data and Additional Standards
 - Process Automation
 - SDR Host Migration

• Progress



Study Design to EDC in <u>4 Easy Steps</u>

•••1. Build a study using Trials.ai

Trials.ai's unique interface allows scientists to use natural language to construct a structured USDM compliant protocol specification.

	Trial Designer - trials.ai						
	Study Concepts ×			Screening Period	Treatment Period	Followup Period	Add Peri
	Ddf DEMO 001	Sc	chedule 1	Visit 1	Visit 2	Visit 3	
	Study Setup						
	Treatments		Adverse Events				
	Objectives & Endpoints		physical examination				
	Study Design		ECG Triplicate				
	Eligibility Criteria		Vital Signs				
0	Schedule Of Activities		Medical History				

3. Merative connects to the SDR

Merative Clinical Development provides users the ability to connect to their SDR and select study definitions and versions.

Merative Clinica	Development	SDR Demo						
Build: Import B	uild from SDR							
DR Import:								
Name Filter	TRIALSAI: Phas	ie 2						
SDR Study	TRIALSAI: Pha	se 2 Study of ISIS 6	81257 (AKCEA-	APO(a)-LRx) ir	Participants With	h Hyperlipoproteir	nemia(a) and Cardiovascular Disease (1cc62b59)	~
Upload Version	v v17	b		_				7
	v16							
	v15							
	v14							

2. Trials.ai pushes to the SDR

Trials.ai utilizes the complete set of data elements defined by the USDM, connects to the SDR and pushes the study design specification for consumption.

TransCelerate	
NOME STUDY DEFINITIONS	
Welcome to the Digital Data Flow Study Definitions Repository Dashboard!	
Recent Activity	Last Modified
TRIALSAL Phase 2 Study of ISIS 681257 (AKCEA-APO(e)-LRu) in Participants With Hyperlipoproteinemia(a) and Cardiovascular Disease_Version 17	2022-09-26-22:09:18
TRIALSAL Phase 2 Study of ISIS 681257 (AKCEA-APO(a)-LRx) in Participants With Hyperlipcoroteinemia(a) and Cardiovascular Disease_Version 16	2022-09-26 22:09:16
TRIALSAL Phase 2 Study of ISIS 681257 (AKCEA APO(a) LRx) in Participants With Hyperlipoproteinemia(a) and Cardiovascular Disease _Version 15	2022-09-26 22:09:16
TRIALSAL Phase 2 Study of ISIS 681257 (AKCEA-APD(a)-LRx) in Participants With Hyperlipoproteinemia(a) and Cardiovascular Disease_Version 14	2022-09-26 22:09:15
TEAL DAL Blazz 9 Onub of IDE 201957 (AVCEA ADD/a), Do in Deticipants Mith Monatingentainents(a) and Conference das Disease Viscoin 12	0030.00.06.02-02-15

4. Merative builds the EDC

Merative Clinical Development imports study design from SDR and automatically builds EDC study design with full schedule of activities and associated eCRFs.

Merative Clinical Development	TRIALSAI Phase 2 Study of ISIS 6812	Define V Bi	ulid V Modules V Prepare V Dev Mode V
× E Revision: Imported	SDR Revision / Study events / Visit 1		
😧 Study event schedule	1 II Adverse Events	1	
screening period	2 II: Physical Exam		Adverse Events
followup period	3 II ECG Test Results		
Study events ^	4 II Vital Signs	1	What is the adverse event term? *
visit 2	5 II Medical History		
visit 3			
🖹 Forms 🗸			What is the date the adverse event started? *
00 Cartlane			what is the wate the auverse event started? *

cdisc

Mapping Trials.ai design to Merative EDC

.......

Ddf DEMO 001	Schedule 1 T	init 1 Viela 2	Mail 2	HOME STUDY DEFINITIONS		
Study Setup	VISI	sit i yisit z ;	VISICO :	Welcome to the Digital Data Flow Study Def	initions Repository Dashboard!	
in Treatments	Adverse Events		2	Dennet Labiday		Loss Medical
🎲 Objectives & Endpoints	physical examination			TRIALSAI: Phase 2 Study of ISIS 661257 (AKCEA-APO(a)-LRx) in Pa	articipants With Hyperlipoproteinemia(a) and Cardiovascular Disease. Version 17	2022.09-26.22.09:18
Study Design	ECG Triplicate			HIMLEM. FILLE 2 Study of ISIS 201257 (MIGEA APO(s) LPU in PS	Merative Clinical Development SDR Demo Define	e V Build V Modules V Prepare V Dev Mode V
Eligibility Criteria	 Vital Signs : 			TRIALSAI: Phase 2 Study of ISIS 681257 (AKCEA APO(a)-LRx) in Pa TRIALSAI: Phase 2 Study of ISIS 681257 (AKCEA-APO(a)-LRx) in Pa	Build: Import Build from SDR	
C Schedule Of Activities	Medical History			TRIALSAI: Phase 2 Study of ISIS 681257 (AKCEA-APO(a)-LRx) in Pa	SDR Import	
Data Analysis				•	Name Filter TRIALSAI: Phase 2	
/	N 1		Study	Title + Version	SDR Study TRIALSAI: Phase 2 Study of ISIS 681257 (AK	KCEA-APO(a)-LRx) in Participants With Hyperlipoproteinemia(a) and Cardiovascular Dis
Device de Alle					v15	
Periods/visi		ISC CRFs			v14	
					¥13	
					v12	
					v12	
Merative Clinical Development	TRIALSAI Phase 2 Study of ISIS 6812	Define V Build V Madules V Pren	sare ∽ Dev Mode ∽			
Merative Clinical Development	TRIALSAI Phase 2 Study of ISIS 6812	Define V Build V Modules V Prep	pare ∨ Dev Mode ∨	Merative Clinical Develop	vrrent TRIALSAL Phase 2 Study of 2515 6812 Define	✓ Build ✓ Modules ✓ Prepare ✓ Dev Mode ✓
Merative Clinical Development X Revision: Imported SDR R	TRIALSAI Phase 2 Study of ISIS 6812	Define V Build V Modules V Prep	oare ∨ Dev Mode ∨	Merative Clinical Develop × III Revision: In	Internet TRIALSAL Phase 2 Study of ISIS 6812 Define mported SDR Revision / Study events / Visit 1	i ∨ Bulld ∨ Modules ∨ Prepare ∨ Dev Mode ∨
Merative Clinical Development X Revision: Imported SDR R	TRIALSAI Phase 2 Study of ISIS 6812 vision / Study event schedule	Define V Build V Modules V Prep	oare ∨ Dev Mode ∨	Merative Cilicial Develop	error TRIALSAI Phase 2 Study of 1515 6612. Certre mponed SCR Revision / Study errors / Visit 3	Nodules V Prepare V Day Mode V
Merative Clinical Development X Revision: Imported SDR R Study event schedule	TRUALSAL Phase 2 Study of 1515 6532	Define V Build V Hodules V Prep	pare V Dev Mode V	Mentrive Childred Develop × III Revision: II · Study ents Schedul	mitint TREALSAL Phase 2 Study of 5155 6822 Curine miponed SDR Revision / Study events / Visit 1 e 1 II Adverse Events I	Build Modules Pepare Day Mode
Merative Clinical Development Revision: Imported SDR R Study event schedule screening period	TRIALSAI Phase 2 Study of ISIS 6832 vision / Study event schedule Collapse all Q. Search	Define V Build V Modules V Prep	oare ∽ Dev Mode ∽	Merstva Citiaca Develop K III Revision: II Study event schedul screening partical tractment partical	TELALSAL Phase 2 Study of 1515 6832_ TELALSAL Phase 2 Study of 1515 6832_ TELALSAL Phase 2 Study events / Visit 1 A decrease Events D B Adverse Events D B Physical Exam D	Build Modules Prepare Dev Mode >
Merstive Clinical Development Revision: Imported SDR R Study event schedule screening period treatment period	TR/ALSAL Phase 2 Study of JS15 6632	Define Y Build Y Modules Y Prep	Dev Mode V	Kerstive Chicka Lowenio X Kerston: In Study event schedul screening period trattmet period followe period		Build Modules Prepare Dav Mode
Merative Clinical Development Revision: Imported SDR R Study event schedule screening period treatment period followup period	TREALSAL Phases 2 Strudy of JS15 6532	Define V Build V Modules V Prep	arrs V Dev Made V Title	Kerster Cloicel Develop X C Kevston: In Story version: In treatment period treatment period Story version Story version	VI2 Centre TELLISAT Phase 2 Study of JS15 A032 Centre Centre mported SCR Revision / Study events / Visit 1 Imported SCR Revision / Study events / Visit 1 I 1 Adverse Events Imported SCR Revision / Study events / Visit 1 I 2 Physical Exam Imported SCR Revision Imported SCR Revision J 1 ECG Test Revision Imported SCR Revision Imported SCR Revision Imported SCR Revision J 1 ECG Test Revision Imported SCR	Buld Modules Prepare Dev Mode
Heritiva Cilicical Development Revision: Imported SDR R G Study event schedule screening period treatment period Study events	TEPALSAL Phase 2 Study of 1515 6532 Nition / Study event schedule Collapse all Q. Search Name ~ screening beriod	Define V Build V Hodules V Prep	are V Dev Mode V Trite Screening Period	Marstov Chicks Develop X Revision: D Revision: D Screening partici- tication partici-	VI3 Centre mported SDR Revision / Study of JSIS 6022_ Centre mported SDR Revision / Study events / Visit 1 I I II Adverse Events I 2 IPsyscal Exam II 3 IE CO Text Revists II 4 II Vial Signs II	Build Modules Prepare Dev Mode Adverse Events What is the adverse event term? *
Herstiva Clinical Overlagment X Revision: Imported SDR R Study event schedule screening period treatment period Study events vinit 1	TRIALSAI Phase 2 Study of 1515 6832 vision / Study event schedule Collapse all Q. Snarch Name Collapse all Screening Berlind VIII	Define V Build V Modules V Prep	Title Screening Period Visit 1	Merstrus Cificial Develop K ID Revision: In Study event schedul screening pariod treatment pariod tollowop period Study events visit 1 visit 2	vr3 TREALSALPhase 2 Study of 1515 6632 Control mponed SDR Revision / Study events / Visit 1 e 1 Adverse Events 1 2 Il Physical Study 1 I 3 IL ECO Trest Revists 1 I 4 IVal Signs 1 I Adverse IV 1 5 II Medical Histery 1 I Adverse IV 1 I	Build Modules Pregare Day Mode Adverse Events
Merstiva Clicical Cevelopment X Revision: Imported SDR R Study event schedule A screening period followup period followup period Study events visit 1 visit 2	TRIALSAL Phase 2 Study of ISIS 6832	Define V Build V Modules V Prep	Title Screening Period Visit 1 Treatment Period	Mersilve Cloiced Develop X II Revision: In C Study version: Standard Screening particular treatment particular Study version Visif 1 visit 2 visit 3	V12 Octore ITERALSALT Phase 2 Study of 1515 6612 Certree Certree mponed 500 Revision / Study events / Visit 3 Imponed 500 Revision / Study events / Visit 3 a 1 Il Adverse Events Imponed 500 Revision / Study events / Visit 3 a 2 Physical Exam Imponed 500 Revision Imponed 500 Revision 3 III Co Trast Revision Imponed 500 Revision Imponed 500 Revision Imponed 500 Revision 4 III Visid Stars Imponed 500 Revision Imponed 500 Revision Imponed 500 Revision	Build Modules Prepare Dav Mode Adverse Events What is the adverse event term?
Hernio Cilical Svelopment Revision: Imported SDR R Streening period treatment priod followup period Study events visit 1 visit 2 visit 3	TREALSAL Phase 2 Study of SISE 6922 vision / Study event schedule	Define V Build V Modules V Prep	Trite	Kenston Citical Develop X In Revision: In State years bedi screening particle treatment particle treatment particle treatment particle treatment particle visit 1 visit 2 visit 3 Forms	VI3 Certon mported SCR Revision / Study of JS15 Ad32 Certon mported SCR Revision / Study events / Visit 1 I I II Adverse Events I 2 IP Physical Exam I 3 II EG Task Reviston I 4 IV task Signs I 5 II Medical History I	Build Modules Prepare Day Module I Adverse Events I What is the adverse event term? * I What is the date the adverse event started? *
Heritiva Cilicial Development Revision: Imported SDR R G Study event schedule screening period treatment period Study events visit 1 visit 2 visit 3 P Forms	TEPALSAL Phase 2 Study of 1515 6832- Nition / Study event schedule Collapse all Q. Smarch Name Collapse all Q. Smarch Name Screening Deriod Yost1 Testment period Yost2	Define V Build V Hodules V Prop	Arris V Doy Mode V Tritle Screening Period Visit 1 Treatment Period Visit 2	Marstrue Childed Develop X Revision: II Revision: II Sections period screening period testment period followup period visit 1 visit 2 visit 3 Parms Sections	VI3 Centre mported SDR Revision / Study of JSIS 6022_ Centre mported SDR Revision / Study events / Visit 1 1 1 1 B Adverse Events 1 2 1 Physical Exam 1 3 1 ECG Text Revists 1 4 1 Vial Sign 1 5 1 Medical Hittery 1	Duld Modules Prepare Dav Mode
Herstruc Clinical Coverlagment Revision: Imported SDR R Study event schedule screening period treatmert period followap period Study events visit 1 visit 2 visit 3 Escretors	TRIALISAL Phase 2 Study of 1515 6812 vision / Study event schedule Collapse all Q. Search Name Collapse all Q. Search Sectod Sectod Visit 1 Collapse all C. Search Visit 2 Collapse al	Define V Build V Modules V Prep	Arris Cey Mode C Trite Screening Period Visit 1 Treatment Period Visit 2 Followup Period	Arstroc Clinical Develop X ID Revision: In Stady event schedul screening pariod tollowup pariod tollowup pariod stady events visit 1 visit 2 visit 3 P Forms E Sections G Questions		Build Modules Pregare Dav Mode Adverse Events What is the adverse event term? * What is the date the adverse event started? *
Meratus Cilicical Overlapment × Revision: Imported SDR R Study event schedule screening period total readment period followap period Study events ~ visit 1 visit 2 visit 2 visit 3 Perms ~ Sections @	TELALSAL Phase 2 Study of SIS 6922 vision / Study event schedule Collapse all Q. Search in Anne v screening period visit 1 visit 2 č information joint 2 joint 2 joint 2 joint 2 joint 2 joint 2	Define V Buld V Modules V Prep	Arrew Dev Made V Title Screening Period [Visit 1 [Treatment Period] Visit 2 [Pollowup Period]	Herster Cloice Develop X I Revision: In C Stay version: Screening particular screening particular treatment particular visit 1 visit 2 visit 2 visit 3 P Ferms EI Sections Codeliss	vira Centre TRIALSAI Phase 2 Study of 1515 6432 Centre mponted Stüf Revision / Study events / Visit 3 I I Il Advense Events I 2 Physical Exam I 3 Il E Cia Tesi Revision I 4 IVad Signs I 5 Il Medical Histery I	Build Modules Prepare Dave Mode Adverse Events What is the adverse event term? What is the date the adverse event started?
Meritive Cilicical Development X Revision: Imported SDR R G Study event schedule screening period treatment period followup period Study events visit 1 visit 2 visit 3 Proms Questions E Codelists	TERALESAL Phase 2 Study of 1515 6832 Wition / Study event schedule Collapse all Q. Search Image: Search <td>Define V Build V Modules V Prop</td> <td>Arre V Dev Hode V</td> <td>Aesthol Childed Develop X Aesthol Childed Develop X Aesthole II Storeening period screening period testment period testment period testment period store visit 1 visit 2 visit 3 Forms Sections Codelins Codelins Codelins</td> <td>VI2 Certon mported SDR Revision / Study of JS15 6022 Certon 1 If Adverse Events I 2 IP Paysoal Exam I 3 If EG Texi Reviston II 4 Vial Signs II 5 If Medical Hittery II</td> <td>Outd Modules Prepare Dav Module</td>	Define V Build V Modules V Prop	Arre V Dev Hode V	Aesthol Childed Develop X Aesthol Childed Develop X Aesthole II Storeening period screening period testment period testment period testment period store visit 1 visit 2 visit 3 Forms Sections Codelins Codelins Codelins	VI2 Certon mported SDR Revision / Study of JS15 6022 Certon 1 If Adverse Events I 2 IP Paysoal Exam I 3 If EG Texi Reviston II 4 Vial Signs II 5 If Medical Hittery II	Outd Modules Prepare Dav Module
Merstrue Clinical Oevelopment X Revision: Imported SDR R Gottade Standard SDR R Standard SDR R Stady event schedule Stareating period treatment period followay period Study events N visit 1 visit 2 visit 3 Sections Ø Sections Questions E Gotelitis Measurement units	TEPALSAI Phase 2 Study of 1515 6832 vision / Study event schedule Collapse all Q. Snarch Name v Screening Deriod Visit 2 Collapse all Screend Visit 3	Defre Duld Pedules Prep	Arris Cey Mode C Title Screening Period Visit 1 Treatment Period Visit 2 Pallowup Period Visit 3	Konstruct Chinical Develop X Revelop: 1 Study event schedul screening pariod totowup pariod 	TREALSAL Phase 2 Soudy of 1515 6632_ Certre TREALSAL Phase 2 Soudy of 1515 6632_ TREALSAL Phase 2 Soudy o	• Build Modules Pregare Dave Model
Maratus Cillocal Development X Revision: Imported SDR R Study event schedule A screening period followap period total veent schedule A visit 1 visit 2 visit 2 visit 3 B Sections C Questions Codelists Massement units A Revision permissions	TELALISAL Phase 2 Study of SIS 6822- wition / Study event schedule Collapse all Q. Search Collapse all Q. Search Screening period Screening	Define Buld Hodules Prep	Arre V Dev Mode V	Version Cloics Develop X I Revision: I G Stady version: Scheduler treatment period treatment period Visit 1 visit 2 visit 3 P Forms ES Sectors G Sectors G Sectors G Sectors G Sectors Revision Permission Av Revision permission		End Modules Prepare Dave Mode
Heritiva Cilicical Development X Revision: Imported SDR R Study event schedule A screening period Intervented period Study events A visit 1 visit 2 visit 2 visit 3 Premise Codelistis E Sections Codelistis Measurement units Av Av Revision permissions Av	TELALESAL Phase 2 Study of 3515 6232 vision / Study event schedule Collapse all Q. Search Name v Screening, period visit1 v Iteration period visit2 iteleosup period visit3	Define V Build V Modules V Prep	Trite Trite Screening Period Visit 1 Treatment Period Visit 2 Followup Period Visit 3	Kentho Cilical Develop X Constraints Kenthon II Stateware schedul screening period telawage period telawage period visit 1 visit 2 visit 3 Forms Sections Codeliss Codeliss Kexision permission	VI2 Visit TBLALSAL Phase 2 Study of JS15 Ad32 Certors mported SCR Revision / Study events / Visit 1 I I II Adverse Events I 2 IP Paysical Exam I 3 II: ECG Task Revision I 4 IV task Signs I 5 II: Medical Hintery I	Build Modules Prepare Day Module >







There will be tangible benefits

□ SDR is the "great equalizer"

- Not beholden to any one system
- Study design/build skill sets less system-dependent

□ Increased industry alignment – "single method" anyone?

□ Build "once and done"

□ Stop shuffling the work around – imagine actually having *less* work?



Challenges to be overcome as DDF advances

Other considerations:

- **Troubleshooting complexity** due to incorrect credentials or some issue at the SDR level (incoming from upstream system or from source)
- Change management needs to be combo of tech & process





Expand the concept and integrate with other parts of the process

- Move beyond only Schedule of Events & CRF integration
- Flow into: eConsent Stratification Randomization

Bi-directional data flow







Jennifer Duff – <u>Jennifer.duff@merative.com</u> Mark Laney – <u>mark.laney@merative.com</u>



