DDF Phase 3 Public Information Webinar

14th September 2023

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TransCelerate’s DDF Initiative
TransCelerate – A Catalyst for Collaboration

We are a not-for-profit entity created to foster collaboration. Our mission is to collaborate across the global biopharmaceutical R&D community on solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

Our Strategic Priorities Guide Us In Achieving Our Goals

- Harmonize Process & Share Information
- Improve the Patient & Site Experience
- Enhance Sponsor Efficiencies & Drug Safety
Digital Data Flow Ambition

**Digital** - standard representation of study protocol
- structured
- machine readable
- executable

**Data Flow** – industry-wide interoperability
- exchange of data
- non-cooperating organizations
- minimal effort

**Documents to Data / Write Once, Read Many**

**TODAY:** Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems

**TOMORROW:** Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems

Eliminate non-value added activities, work smarter not harder
Enable automation of downstream study startup and conduct processes
Create foundation for study design analytics insights
DDF Subteams and Delivery

**Standards**
- USDM Reference Architecture
- UML Model
- API Specs
- Controlled Terminology
- Implementation Guide

**Delivery/Build**
- Study Definitions Repository – Reference Implementation
- Infrastructure as Code Scripts
- Documentation

**Change & Engagement**
- Solution Provider Collaboration Forum
- Sponsor Persona Toolkits
- HA Strategy
- Communications and Events

**Governance**
- Sustainable Governance Model
DDF Future Value Streams

Complete Protocol Digitization & Regulatory Alignment
• Complete (100%) digitization of all protocol elements in alignment with M11
  • Automate production of SDTM Trial Design Domains and Registry Protocol Submission.

Alignment with Point of Care
• Alignment of USDM and FHIR/ResearchStudy resources for study workflow and eSource

Expand Downstream Connectivity
• Data flows to “protocol consuming” operational systems (e.g. CTMS, IVRS, DCT, eConsent)
  • Work collaboratively with solution providers identify requirements for USDM
## DDF Comms, Events & Webinars

### Upcoming Events, Webinars & Conferences

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<td>CDISC Webinar: DDF Phase 3 Informational</td>
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<td>PHUSE SDE Copenhagen: Automation – Work Smarter Not Harder!</td>
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- **Major/Interactive Event**
- **General Awareness**
- **Virtual option available**
Introduction
Digital Data Flow

• Phase 1
  • Base model design
    • UML
    • API
    • Controlled Terminology
  • Topics
    • Objectives and endpoints
    • High Level Study Design
    • Eligibility criteria
    • Activities and assessments
    • Basic schedule of activities and assessments
    • Basic data collection configuration related to activities and assessments

• Phase 2
  • Extended model
    • UML
    • API
    • Controlled Terminology
    • USDMIG
    • Example Data
  • Topics
    • Enable greater population of study set-up elements
    • Represent structured study design information for more complex trials
      • Handling of complex study timing
    • Support electronic data capture (EDC) automation
      • Expand model to include Biomedical Concepts
    • Demonstrate population of the TransCelerate Common Protocol Template (CPT)
    • Demonstrate population of SDTM Trial Design Domains
Work Areas

DDF3

USDM RA  Conformance Rule Development  Biomedical Concept Development
CDISC Study Definition Repository RA Deliverables

- Unified Study Definitions Model (USDM) Class Diagram
- Application Programming Interface (API) Specification
- CDISC Controlled Terminology
- USDM Implementation Guide
DDF 3 USDM Scope

- Represent ICH M11 in USDM
- SDTM Trial Design Population
- Clinical Trial Registry Population
- Complex Studies/Cohorts
- Model Enhancements
DDF 3 USDM Scope

• Include breadth of ICH M11 into the USDM
  • Narrative Content
    • Covers free text parts of the M11 specification (i.e., without data elements)
  • Structured content
    • Using data elements to build sections of text
    • Individual structured elements (e.g., Study acronym, phase)

• SDTM Trial Design Population
  • Population of the planning parts of the SDTM trial design information
  • Some mapping performed in DDF 2
  • Additional mapping to allow population of existing SDTM trial design information (particularly the FDA required parameters)
  • Identification of new alignments between ICH M11 and SDTM trial design artefacts
    • What other trial design elements from the ICH M11 protocol could we represent in SDTM T domains

• Clinical Trial Registry Population
  • Expand on existing CTR.xml standard
  • POC to show population of structured fields from USDM for registering and updating studies in clinical Trial registries
DDF 3 USDM Scope

• Complex Studies, Complex Cohorts
  • Enhancements to ensure the model can hold complex study designs with complex cohorts
  • Allow for more modern protocol designs (e.g., basket trials, adaptive trials)
  • Include feedback from users of USDM v2.0

• Model Enhancements
  • Create a true logical data model with logical relationships that are visible and understandable with a separate document that details the API step to enable serialization to produce the required JSON
  • Improve element naming for consistency and standardize some elements within each class (e.g., name, description fields)
  • Improve general readability of the UML model
DDF 3 USDM Supporting Documentation

• USDMIG
  • Improve USDMIG content based on user feedback
  • Add additional Guidance for new elements added to the model

• USDM Test Data
  • Maintain test data developed during DDF2 to include new elements added to the model
  • Develop new test data for more complex study designs
Conformance Rule Development
DDF 3 and CORE

DDF 3 will focus on development of the rule specifications.

Later phases will focus on executable conformance rules and adaptation of CORE to work with DDF.

* CDISC Open-Source Alliance
DDF 3 and CORE

- Conformance currently part of the USDM API specification
- In-line with CDISC strategy for other standards the future intent for DDF is to have conformance rules specified in the library and executable through CORE
- DDF 3 limited to Excel Rule Specification only
  - Develop a representative set of conformance rules covering the breadth of the different types of rules expected to be required for use and several examples of elements using that type of rule required for DDF conformance
- Future phases may include development of a full set of conformance rule specifications alongside executable rules and CORE updates to work with DDF
Biomedical Concept Development
Biomedical Concept Development

- **DDF 2**
  - Integration of the CDISC BC model into USDM to support EDC automation
  - Development of BCs to support a COVID protocol
Biomedical Concept Development

• DDF 3
  • Development of additional biomedical concepts to cover the CDISC Pilot Study (LZZT)
  • Allows for a full exemplar USDM protocol Design
  • LZZT used by other groups so allows for further alignment
Process and Timelines
CDSIC Standards Development Process (COP-001)

- **Stage 0a**: Scoping and Planning
  - Sprint Scoping and Planning

- **Stage 0b**: Sprint Scoping and Planning
  - Identification and modeling

- **Stage 1**: Development of draft standards

- **Stage 2**: Internal Review

- **Stage 3a**: Public Review

- **Stage 3b**: Publication

Parts of Stage 0b – 3a take place for each draft release.
- After Stage 0a, the sprints begin and a small scoping effort happens as part of the planning for each sprint
- An Internal review step happens after each draft release.
# Development and Review

## 2023

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### Notes
- Development
- Continuous Internal Review
- Public Review

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DDF 3 USDM Scope

- Represent ICH M11 in USDM
- SDTM Trial Design Population
- Clinical Trial Registry Population
- Complex Studies/Cohorts
- Model Enhancements
Next Steps – Phase Three

1. Baseline model for specifying a study in digital format
   - Model supports use of a CRF link to specify which forms to use in EDC.
   - Handles simple study designs

   - Consume digitized study specification from an upstream source e.g., study builder
   - Store, view and search study concepts
   - Downstream EDC systems may pull study specification to aid in set-up

2. Improved support for complex study designs with a fully specified digitized Schedule of Activities (SoA)
   - Model supports the identification of the appropriate CRFs for data collection to enable automated, faster configuration via use of Biomedical Concepts
   - Improved CPT alignment
   - Initial ‘T’ Domain support

   - Downstream vendors can readily consume the SoA from the SDR
   - Sponsor system admins can perform a visual check that SoA data received from an upstream system displays an accurate, human-readable SoA table
   - Opportunity to aggregate robust historical protocol information to support analytics to drive smart design and assess risk

3. Focus for Phase 3 is currently being determined. Current expectations are:
   - Expand ability to handle increasingly complex studies
   - ICH M11 & CPT alignment

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**M11 Is …**

**ICH CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)**


**INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE**

**ICH HARMONISED GUIDELINE**

**CLINICAL ELECTRONIC STRUCTURED HARMONISED Protocol (CeSHarP)**

**M11**

Draft version

Endorsed on 27 September 2022

Currently under public consultation

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Assembly to the regulatory authorities of the ICH regions for internal and external consultation, according to national or regional procedures.

**Defines the background, purpose and scope**

**The specification of the Protocol Document Template that contains embedded data elements**

**Provides a set of data element definitions aligned with the template specification**

**CDISC - Clear Data Clear Impact**

**DDF Phase 3 Public Information Webinar**
**M11 Simple Example**

**Template Specification**

- **Protocol Full Title:**
  - The protocol should have a descriptive title that identifies the scientific aspects of the trial sufficiently to ensure it is immediately evident what the trial is investigating and on whom, and to allow retrieval from literature or internet searches.

- **Sponsor Confidentiality Statement:**
  - Insert the Sponsor’s confidentiality statement, if applicable, otherwise delete.

- **Protocol Number:**
  - A unique alphanumeric identifier for the trial, designated by the Sponsor, is a standard part of trial data, and should be included for each trial.

- **Version:**
  - Version

- **Amendment Number:**
  - An optional field for use by the Sponsor at their discretion.

- **Term (Variable):**
  - **Trial Phase**
  - **Description of Trial Phase Other**

- **Acceptable entries are:** “Early Phase 1”, “Phase 1”, “Phase 1/Phase 2”, “Phase 2”, “Phase 2/Phase 3”, “Phase 3”, “Phase 4”.

**Technical Specification**

- **Term (Variable):**
  - **Trial Phase**

- **Data Type:**
  - Pick list

- **Topic, Value or Header:**
  - D

- **Definition:**
  - For trials combining investigational drugs or vaccines with devices, classify according to the phase of drug development.

- **User Guidance:**
  - Required

- **Cardinality:**
  - Title Page

- **Relationship content from ToC representing the protocol hierarchy:**
  - Early Phase 1
  - Phase 1
  - Phase 1/Phase 2
  - Phase 2
  - Phase 2/Phase 3
  - Phase 3
  - Phase 4
  - Other

- **Business rules:**
  - Value Allowed: yes
  - Relationship: n/a
  - Concept: Protocol short title

- **Duplicate field in other sections:**
  - [Protocol Full Title]
  - [Protocol Number]
  - [Sponsor Confidentiality Statement]
  - [Protocol Number]
  - [Description of Trial Phase Other]
  - [Trial Phase]

**CDISC - Clear Data Clear Impact**

**DDF Phase 3 Public Information Webinar**
Alignment with M11 and the eProtocol document template providing a full eProtocol and the framework for future development

Phase four and onwards allows us to add detail turning text-based elements into structured, machine-readable, elements as requirements and need demands

Depth driven by individual use cases. Some capability exists today, can be expanded incrementally or in one phase

Breadth driven by the bounds of the M11 technical Specification

Phases

1. CTR
   - SDTM 'T'
   - Domain Support
2. Use Case
3. Use Case
4. Use Case

Build the solid foundation for all subsequent model development. Provides the base model

The addition of complex study designs providing the core of the model

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Shift of Focus

• Phases One & Two
  • Focused on the structured elements of the protocol, e.g. the Schedule of Activities (SoA)
  • The protocol document was an external entity into which the structured content could be exported

• Phase Three
  • Now contains structured and unstructured elements
  • The entire protocol document is held within the USDM
  • Allows for the protocol document to be generated from the model
M11 Template Example Document

• First attempt to create a protocol document from the USDM, both structured [non-narrative] and unstructured [narrative text] content.
• Functionality has been added to the Excel test data tool.
• More work is needed, this is very much a first draft.

5.1 Selection of Trial Population

5.2 Rationale for Trial Population

5.3 Inclusion Criteria

Patients may be included in the study only if they meet all the following criteria:

[1] Males and postmenopausal females at least 50 years of age.
[2] Diagnosis of probable AD as defined by National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the Alzheimer's Disease and Related Disorders Association (ADRDA) guidelines (Attachment LZZT.7).
[5] CNS imaging (CT scan or MRI of brain) compatible with AD within past 1 year. The following findings are incompatible with AD:

a. Large vessel strokes
   1. Any definite area of encephalomalacia consistent with ischemic necrosis in any cerebral artery territory.
   2. Large, confluent areas of encephalomalacia in parieto-occipital or frontal regions consistent with watershed infarcts. The above are exclusionary. Exceptions are made for small areas of cortical asymmetry which may represent a small cortical stroke or a focal area of atrophy provided there is no abnormal signal intensity in the immediately underlying parenchyma. Only one such questionable area allowed per scan, and size is restricted to ≤1 cm in frontal/parietal/temporal cortices and ≤2 cm in occipital cortex.

b. Small vessel ischemia
   1. Lacunar infarct is defined as an area of abnormal intensity seen on CT scan or on both T1 and T2 weighted MRI images in the basal ganglia, thalamus or deep white matter which is ≤1 cm in maximal diameter. A maximum of one lacune is allowed per scan.
   2. Leukoariosis or leukoencephalopathy is regarded as an abnormality seen on T2 but not T1 weighted MRIs, or in CT. This is accepted if mild or moderate in extent, meaning involvement of less than 25% of cortical white matter.
ICH M11, CDISC & HL7

• “FHIR-based exchange standard for ICH’s Clinical electronic Structured Harmonised Protocol (CeSHarP), aligned to CDISC standards”

• The USDM and CDISC CT will be used in the project

• Initial project discussions have been underway for a few months

For Immediate Release

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Vulcan FHIR® Accelerator Connects CDISC, HL7, and ICH M11 in a Project to Digitize Exchange of Clinical Research Protocols

HL7 Vulcan and CDISC are announcing a project that will deliver an electronic exchange standard for the ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

Ann Arbor, MI, and Austin, TX — June 6, 2023 — A structured, harmonized, digitized protocol accessible to the biopharmaceutical industry and to researchers in the care setting will enable transformations to improve clinical research. The project announced by HL7 Vulcan and CDISC will build on work products of ICH M11 to accelerate this vision. Vulcan is an HL7® FHIR Accelerator dedicated to connecting clinical and translational research to clinical care through Fast Healthcare Interoperability Resources (FHIR®). CDISC is a non-profit standards development organization that develops standards that support acquisition, exchange, submission, and archive of biopharmaceutical data. CDISC is also a member of Vulcan. ICH M11 is the topic of the International Council for Harmonization to create a Clinical electronic Structured Harmonised Protocol (CeSHarP).

“The project marks an important milestone in the long journey towards a digital protocol,” said Vulcan Co-Chair, Amy Cramer. “Over the years, various organizations have contributed key building blocks. Vulcan is pleased to serve as a convener where contributors across the global research community can collaborate towards this shared and important goal.”

“We are looking forward to partnering with ICH M11 and HL7 on this important project that aims to enable the digital transformation of protocols in support of automation,” said David Evars, President and CEO, CDISC. “This project represents another step in CDISC’s strategic evolution to embrace governance of clinical research information standards, not just clinical data standards.”
USDM Meets M11

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SDTM Trial Design
USDM v2 SDTM Trial Design Activities

- Initial investigation into automated creation of SDTM Trial Design datasets.
- USDMIG documented a list of published Trial Summary (TS) parameters and their mapping to USDM elements (entities, attributes, or valid values)
- DDF Phase 3 will expand on this initial work

https://github.com/cdisc-org/DDF-RA/blob/v2.0.0/Deliverables/IG/USDM-IG.pdf#section-3.1 SDTM and SDTMIG
SDTM Trial Design - activities

- Weekly alignment meetings
- Mutual education of SDTM vs USDM specialists
- Explore SDTM trial design domains
- Check current overlap and mapping from USDM to SDTM Trial Design domains
- Check corresponding M11 requirements and overlap with SDTM
- Suggest additions to USDM
USDM recommendations

• SDTM TS domain
  • Add current TS parameters that are required by FDA to USDM
  • Add additional corresponding M11 parameters to USDM
  • The following USDM classes are affected
    • Study / Study Design
    • Population
    • Intervention
    • Indication

• SDTM TI domain
  • Include Eligibility Criteria in USDM and align with TI

• Other trial design domains
  • Alignment in progress
Available Resources
Digital Data Flow

Overview  Participate  Webinar  Release Information  Files  FAQ  Contact Us

Published Date: 27 June 2023

CDISC is collaborating with TransCelerate as a part of TransCelerate’s Digital Data Flow Project to develop a Study Definition Reference Architecture that will serve as a standard model for the development of conformant study definition technologies, including the TransCelerate-developed Study Definitions Repository Reference Implementation. Additional information can be found on the TransCelerate Digital Data Flow Solutions page.

Digital Data Flow - Phase 1 (July 2021 - July 2022)

The Reference Architecture (RA) will provide solution architects with a common vocabulary, reusable designs, industry best practices, standards, and general implementation guidance. The RA is not a solution architect and is not implemented directly but constrains concrete solution architectures with the purpose of promoting the development of conformant solution architectures that enable interoperability across multiple systems in a clinical study, improve efficiency, and reduce cycle times.

Please refer to the Project Deliverables tab for more information on the standards developed during Phase 1.

Digital Data Flow - Phase 2 (September 2022 - July 2023)

Continuing the collaboration with TransCelerate, CDISC has further developed the Reference Architecture in a second phase. The anticipated focus of Phase 2 was to update the RA to:

- enable greater population of study set-up elements and represent structured study design information for more complex trials
- support electronic data capture (EDC) automation
- demonstrate population of the TransCelerate Common Protocol Template (CPT)

Digital Data Flow - Phase 3 (Starting July 2023)

Phase 3 of the Digital Data Flow Project is due to commence in July 2023. Additional information on the activities for Phase 3 will be made available shortly.

How to Participate in Phase 3

We invite your organization to participate in Phase 3 of this exciting project. Please visit the DDF Project Participate tab to learn more.

https://www.cdisc.org/ddf
GitHub

https://github.com/cdisc-org/DDF-RA

CDISC - Clear Data Clear Impact   DDF Phase 3 Public Information Webinar
GitHub

https://github.com/cdisc-org/DDF-RA

CDISC - Clear Data Clear Impact     DDF Phase 3 Public Information Webinar
Digital Data Flow (DDF) Team Home
Created by John Owen, last modified on Aug 21, 2023

Welcome to the DDF Wiki Space!
CDISC, in collaboration with TransCelerate's Digital Data Flow Project, is developing a reference architecture, which will serve as a standard model for the development of a Study Definitions Repository. The Repository is a novel central component aimed at facilitating the exchange of structured study definitions across clinical systems using technical and data standards.

Visit the TransCelerate DDF website for more information about the DDF goals

Status

★★★ DDF PHASE III IS NOW IN THE SCOPING AND PLANNING PHASE ★★★

Navigate to the DDF 3 scoping and planning pages

- DDF 3 Scoping
- DDF3 Agendas and Minutes
- DDF 3 Reference Material
- CDISC Internal DDF3
- Action Items
- File lists
- DDF Phase 1
- DDF Phase 2
- CDISC/ICH M11 Internal

Navigate to the DDF Phase 1 Site
Navigate to the DDF Phase 2 Site

https://wiki.cdisc.org/display/TEAMDDF/Digital+Data+Flow+%28DDF%29+Team+Home
Digital Data Flow (DDF) Team Home

Created by John Owen, last modified on Aug 21, 2023

- Welcome
- DDF 2 Project Charter
- Tasks & Milestones
- Development Dashboard

Link to the draft USDM Implementation Guide (USDM-4G) v3.0
Link to USDM GitHub [https://github.com/cdisc-org/DDF-RA]
Internal Review Instructions

Sprint D Deliverables

<table>
<thead>
<tr>
<th>Release</th>
<th>Summary</th>
<th>Link to Materials</th>
<th>UML Changes</th>
<th>CT Changes</th>
<th>API Changes</th>
<th>USDMIG Changes</th>
<th>Test Data Changes</th>
<th>Other Changes</th>
<th>SRE Meeting Link</th>
<th>Internal Review Start</th>
<th>Internal Review End</th>
<th>Internal Review Status</th>
</tr>
</thead>
</table>
| 2.1     | • The UML model has been updated to make it a more logical model and remove API implementation elements and links. • Also some naming changes have been implemented to make the naming more consistent between classes | UML/CT/API | Model split and rename (Delta File) | Model split and rename (Change File) | rename (model split had no impact on the API) | Updated sections to support model split and rename (Revision History) | | | | | | Added

2.2 | • M11 blindness/unblinding content can be represented using the new content class to handle test “blobs” (This content class will also be used to handle other M11 narratives). • Additional naming changes have been implemented to make the naming more consistent between classes (focused on name and description changes) | UML/CT/API | Addition of | Addition of | Addition of | No USDMIG changes for this release | No test changes for this release | | | | | | Active

| Insertion Status | Wednesday | Tuesday | 2023-08-02 | 2023-08-15 |

https://wiki.cdisc.org/display/TEAMDDF/Digital+Data+Flow+%28DDF%29+Team+Home

CDISC WIKI ACCOUNT REQUIRED
CDISC WIKI ACCOUNT REQUIRED

WIKI – USDMIG

https://wiki.cdisc.org/display/USDMIGv3/USDM+Implementation+Guide+%28USDM-IG%29+v3.0

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JIRA – Internal and Public Review Comment Tracking

https://jira.cdsc.org/projects/DDF/summary

CDISC WIKI ACCOUNT REQUIRED
CDISC DDF Workgroups
DDF SME Group

- Meet Weekly
- Provide Expertise
- Discuss USDM Modelling
- Review Draft USDM Releases

CT Registry Population
Structured Text
SDTM Trial Design Population
Complex Studies/Cohorts

Conformance Rules
Biomedical Concepts
Test Data

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Onboarding as a volunteer to the CDISC DDF Team

How to get involved
Process to Request a CDISC Wiki Account

• Create a free cdisclD (if you don’t have one already)
Process to Request a CDISC Wiki Account

• Navigate to the CDISC Volunteer form
  • https://www.cdisc.org/volunteer/form
  • Review of volunteer information
Process to Request a CDISC Wiki Account - DDF

• Navigate to the CDISC Volunteer form
  • Enter your contact information
  • Choose DDF from the team selection
  • Leave TA box blank
  • Enter brief text into the “Specify in which capacity….” box
  • Click Submit
Process to Request a CDISC Wiki Account - DDF

• The CDISC Volunteer coordinator will process your request
  • A CDISC WIKI and JIRA account will be created (if you don’t have one already)
  • You will be added to the DDF mailing list
  • Your request will be forwarded to the DDF PM who will add you to the DDF WIKI group
  • You will then be able to access the DDF WIKI materials and submit comments in JIRA
DDF 3 CDISC US Interchange

Day 2
19 October 2023

11:00 - 12:30
Session 6A: Digital Data Flow

Chair: Bron Kisler, Nurocor

11:00 - 11:30
Automating Study Set-up through Digitalized Protocol
Frederik Malfait, Nurocor

11:30 - 12:00
From Medical Writing to Data Management: Key Considerations for Successfully Adopting the Unified Study Definitions Model (USDM) and Enabling Digital Data Flow (DDF)
Akash Trivedi, Accenture

12:00 - 12:30
Digital Data Flow: Breaking the Document Paradigm with Digital Data Flow from Protocol Design to Electronic Data Capture
Sumesh Kalappurakal and William Illis, Novartis
# DDF PHUSE EU Connect

## Sunday 5 November

<table>
<thead>
<tr>
<th>Time (GMT)</th>
<th>Hall 7</th>
<th>Hall 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>From 14:00</td>
<td>Registration</td>
<td>Handson Workshop</td>
</tr>
<tr>
<td>14:30-16:00</td>
<td>Dazzled and Delighted by Define-XML: Creating Define-XML with Pinnacle 21</td>
<td>Mastering USDH Standards with an Interactive Demo and Handson Workshop</td>
</tr>
</tbody>
</table>

## Tuesday 7 November

<table>
<thead>
<tr>
<th>Time (GMT)</th>
<th>Hall 7</th>
<th>Hall 9</th>
<th>Hall 9A</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>PHUSE 5K Run Around Birmingham - Meet Outside the ICC. All abilities welcome</td>
<td>Phase 3 Public Information Webinar</td>
<td></td>
</tr>
<tr>
<td>09:00-10:00</td>
<td>Keynote Speaker - Gareth Thomas</td>
<td>CDISC - Clear Data Clear Impact</td>
<td>CDISC - Clear Data Clear Impact</td>
</tr>
<tr>
<td>10:00-11:00</td>
<td>Morning Break</td>
<td>TransCelerate</td>
<td>Connect Theme Presentations (DS)</td>
</tr>
<tr>
<td>11:00-12:00</td>
<td>T110: Building a Scalable Utility Service to Manage Multi-Input Applications Available to the Masses</td>
<td>Digital Data Flow - From Vision to Reality</td>
<td>Digital Data Flow - From Vision to Reality</td>
</tr>
<tr>
<td>11:00-12:00</td>
<td>P004: Navigating Unexpected Challenges: Journey Through a Pandemic and International Conflict</td>
<td>CDISC: The Clinical Trial Data Standards Data Workflow</td>
<td>CDISC: The Clinical Trial Data Standards Data Workflow</td>
</tr>
<tr>
<td>11:00-12:00</td>
<td>T115: From Legacy to the Cloud: Nine Years’ Journey Towards a Modern Statistical Computing Environment</td>
<td>More Critical Aspects of Clinical Trials with Much Less Visibility</td>
<td></td>
</tr>
</tbody>
</table>

CDISC - Clear Data Clear Impact  DDF Phase 3 Public Information Webinar

EU 2023
The Clinical Data Science Conference
Questions