

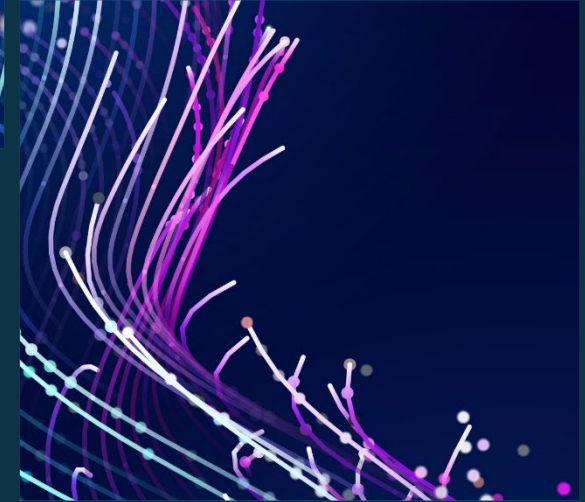


IDRP: Integrated Data Review Plan

Lisa Clough

August 07, 2025

Thank you for joining. We
will be starting shortly.



Agenda

1

Introduction to
IDRP

2

Configuration of
your IDRP

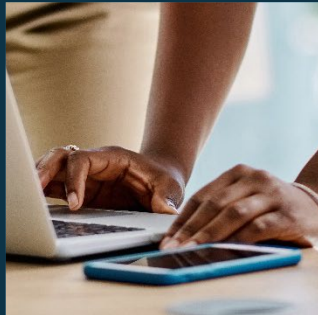
3

Using the IDRP

4

Questions





Introduction to the IDRP

Integrated Data Review Plan



What is the Integrated Data Review Plan?

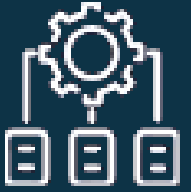
The IDRPs sit within Data Central and enable users to

- ✓ Build
- ✓ Manage
- ✓ Execute

Data Review Plans entirely within illuminate.



What is the IDRП?



Key Capabilities

- **Centralizes and digitizes** data review planning within illuminate
- **Links review objectives** directly to listings, visualizations, and analytics tools
- **Automatically tracks review progress** and completion for audit readiness
- **Highlights objectives** tied to critical data identified during risk assessment
- Supports both **targeted** and **exploratory** review workflows with build-in flexibility



Business Value

- Streamlines review execution and oversight to **reduce cycle time** and manual burden
- Strengthens compliance with **risk-based review strategies** and regulatory expectations



Who can Use and Configure IDRP?

- **USE:** Anyone with the Data Central privilege – review objectives are aligned to your role.
- **CONFIGURE:** Anyone with the Data Central privilege who has been assigned a role other than Read Only.



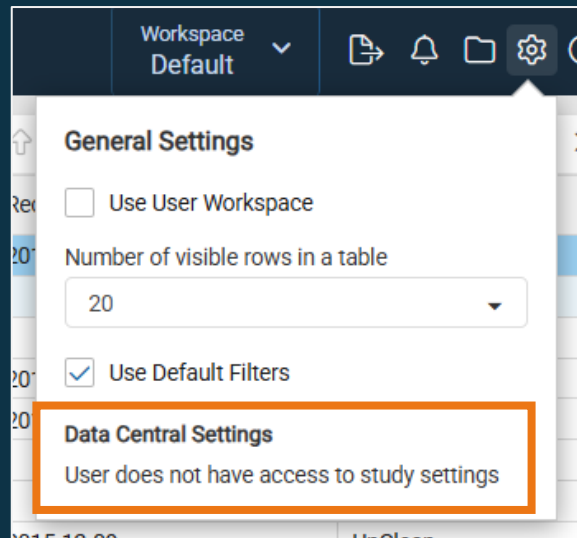


Configuring the IDRP

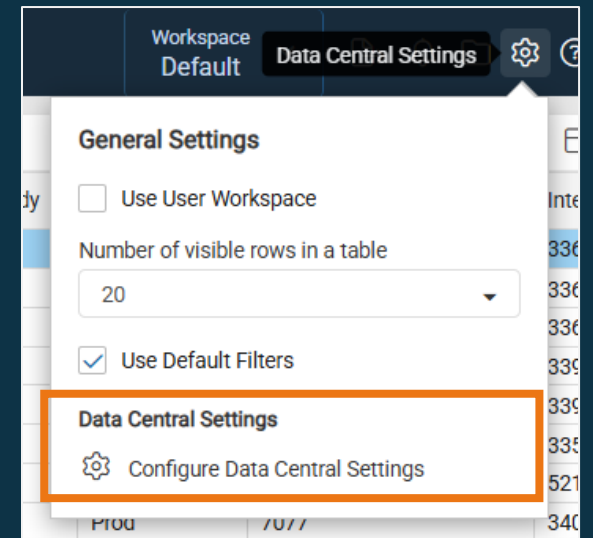


Accessing IDRPs Configuration

If you do not have a Reviewer Role assigned to you, you will not be able to access the configuration window, unless you have Study Configure.



If you do have a Reviewer Role assigned to you, other than Read Only, you will be able to access the configuration window.



Study Configure privilege is not required to build the IDRPs.



Configuring IDRPs

The screenshot shows the 'Data Central Configuration' interface for 'Clintek-011'. The main heading is 'Review Plan'. Below it, there is a section for 'Review Objectives' with a count of 0. The interface includes a search bar, a 'Go to Data Central' button, and a 'Get Template' button. The central message states 'No Objectives Defined' and provides instructions: 'Start building your Review Plan by creating objectives that align with your study's review needs.' Below this, there are three buttons: 'Create Objectives', '-OR-', and 'Import Objectives'. At the bottom, there is a link to 'Download Review Objectives Template'.

- Create Objectives – manually add a review objective
- Import Objectives – import a file with your review objectives
- Download Review Objectives Template (Get Template) – download the excel template



Add Review Objective

Add Review Objective

*** Identifier:** 8/8

*** Review Objective:** 5000/5000

*** Primary Domain:**

Secondary Domain(s):

Field(s):

Priority:

*** Reviewer Role(s):**

*** Programmatic Review Frequency:**

*** Manual Review Frequency:**

Programmatic ⓘ

Review Materials systematically tracked and factor into the Objective Status.

Data Central Listing(s):

eIQ Review Model:

Orchestrator Rule:

Manual ⓘ

Review Materials not systematically tracked but factor into the Objective Status.

Data Central Visualization(s):

Data Central Workspace:

Analytics App:

App Sheet(s):

RBQM Dashboard:

Additional Instructions: 2500/2500

State: ⓘ Inactive

The template includes the same fields as shown here.



List of Review Objectives

Review Plan

[Go to Data Central](#)

Review Objectives 12

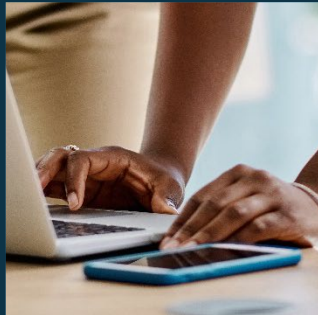
Search [Get Template](#)

<input type="checkbox"/>	Identifier	State	Review Objective	Primary Domain	Secondary Domain(s)	Field(s)	Priority	Reviewer Role(s)	Programmatic Review Frequency	Manual Review Fr
<input type="checkbox"/>	1	✓	If AE Action Taken is drug withdrawn, ou...	Clinical.AE		Clinical.AE.AEACN	High	Data Manager, Medical Data Reviewer	Weekly - Sundays @ 14:15	Weekly - Sundays
<input type="checkbox"/>	2	✓	AE Serious response is Yes, 'Results in D...	Clinical.AE		Clinical.AE.AEOUT, Clinic...	Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sundays
<input type="checkbox"/>	3	✓	Review AE Term, CTCAE Grade, Start Dat...	Clinical.AE		Clinical.AE.AEENDAT, Clin...	Medium	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 11:50	Weekly - Monday
<input type="checkbox"/>	4	✓	Review Adverse Event verbatim term to e...	Clinical.AE		Clinical.AE.AETERM	High	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 00:00	Weekly - Monday
<input type="checkbox"/>	5	✓	1. Ensure there is no AE, Conmed, Conm...	Clinical.AE	Clinical.CM		Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sundays
<input type="checkbox"/>	6	✓	If Other Action Taken = Concomitant Me...	Clinical.AE	Clinical.CM	Clinical.AE.AEACN, Clinic...	High	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 00:00	Weekly - Monday
<input type="checkbox"/>	7	✓	If Ongoing is checked and Resolution da...	Clinical.MH		Clinical.MH.MHONGO	Medium	Data Manager, Medical Data Reviewer	Daily - @ 16:16	Weekly - Tuesday
<input type="checkbox"/>	8	✓	Random one with all review materials wi...	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinical.AE.AEACN, Clinic...	High	Data Manager, Medical Data Reviewe...	Weekly - Sundays @ 16:20	Weekly - Tuesday
<input type="checkbox"/>	9	✓	1. Ensure there is no AE, Conmed, Conm...	Clinical.CM	Clinical.AE, Clinical.CM, C...		Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sundays
<input type="checkbox"/>	10	✓	Ensure there is no visit dates, conmeds, ...	Clinical.AE	Clinical.CM, Clinical.DS	Clinical.AE.AEONGO	Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sundays
<input type="checkbox"/>	11	✓	Random one with all review materials wi...	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinical.AE.AEACN, Clinic...	High	Data Manager, Medical Data Reviewe...	Weekly - Sundays @ 14:15	Weekly - Sundays
<input type="checkbox"/>	12	✓	Review objective with no programmatic ...	Clinical.DM			Low	Data Manager, Medical Data Reviewer	On Data Refresh	Weekly - Tuesday





Using the IDRP



Interacting with your Data Review Plan

The screenshot shows the Data Central interface for study 0003-001. The left sidebar is reorganized into two sections: 'Study Status' and 'Data Exploration'. The 'Study Status' section includes 'Subjects' (380), 'Queries' (0), 'Issues' (37), and 'Review Plan' (3). The 'Data Exploration' section includes 'Protocol Deviations', 'Visualizations', and 'Data'. The main area displays a table of subjects with columns for DM, MDR, SL, and Clean Status. The 'Review Plan' item in the sidebar is highlighted with an orange box.

	DM	MDR	SL					Clean Status
4	743	143	143	30	5	0	0	Do Do
2	2588	497	497	31	5	0	0	Do Do
	460	51	51	3	0	0	0	Do Do
	1248	157	157	6	0	0	0	Do Do
	900	119	119	4	0	0	0	Do Do
	471	58	58	1	0	0	0	Do Do
	4039	525	525	11	1	0	0	Do Do
	4039	525	525	11	1	0	0	Do Do
	490	50	50	2	1	0	0	Do Do
	513	86	86	8	0	0	0	Do Do
	715	105	105	1	2	0	0	Do Do
	8			1	0	0	0	Do Do
	742	124	124	7	0	0	0	Do Do
	268	34	34	5	1	0	0	Do Do
	1182	184	184	3	0	0	0	Do Do
	448	74	74	1	0	0	0	Do Do
	442	81	81	5	0	0	0	Do Do
	538	66	66	3	0	0	0	Do Do
	817	123	123	6	0	0	0	Do Do
	593	77	77	3	0	0	0	Do Do

Left Navigation has been reorganized into two sections:

- Study Status
- Data Exploration

Review Plan provides similar badges:

- Green = Completed Objectives
- Red = Not Started & In Progress Objectives



IDRP Review Plan Options

0003-001

Study Status

Subjects	380	380
Queries	0	0
Issues	37	904
Review Plan	3	9

Data Exploration

- Review Plan Dashboard
- Review Plan Panel
- Review Plan Details

Protocol Dev

Visualization

Data



Review Plan Dashboard

Data Central
Clintek-010
Data Central
Workspace Default

Review Plan 12

Data Manager (DM)

3 of 12 complete

Clinical.AE 7

- 1: If AE Action Taken is drug withdrawn, output AE and ENDDOSE discontinuation reason RISK STATEMENT:
- 2: AE Serious response is Yes, 'Results in Death' and Outcome is not 'Fatal.'
- 3: Review AE Term, CTCAE Grade, Start Date and End Date to ensure no overlapping information for unique Adverse Event Terms.
- 4: Review Adverse Event verbatim term to ensure there is only 1 AE term reported per record.
- 5: 1. Ensure there is no AE, Conmed, Conmed Procedure, Death, Overall survival/progression free survival or date of visit...
- 6: If Other Action Taken = Concomitant Medications: - Ensure at least one CM with an Indication of Adverse Event. - Medication...
- 10: Ensure there is no visit dates, conmeds, procedures or AE dates after date of death.

Clinical.CM 3

Clinical.DM 1

Review Objective Breakdown (Data Manager)

of Objectives

12

Objective Status

5

4

3


Not Started In Progress Complete

of Primary Domains

4

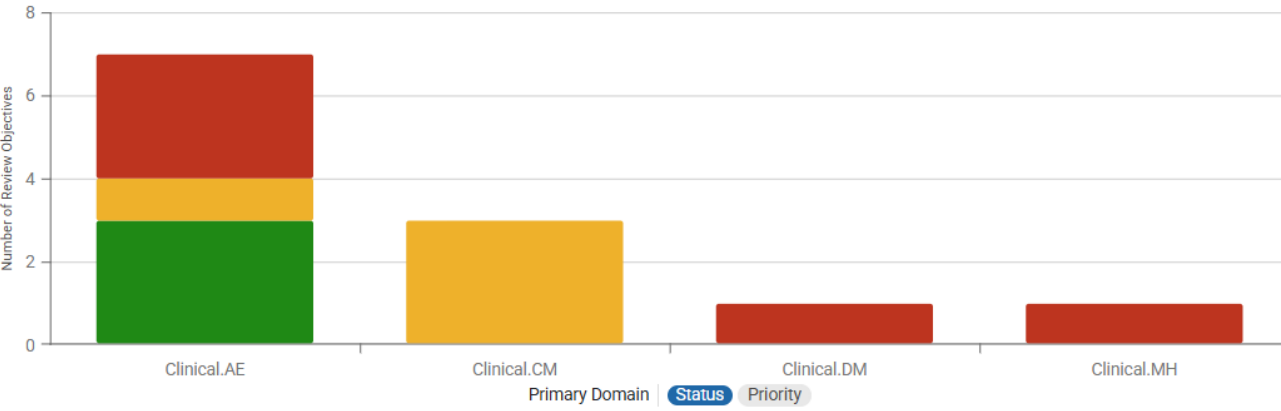
Objectives Breakdown

Status Priority



Complete In Progress Not Started

Objectives By Primary Domain



Primary Domain Status Priority

Complete In Progress Not Started

Review Objectives 12
Search, Filter, Export, Refresh, List, Close icons

Identifier	Review Objective	Status	Primary Domain	Secondary Domain(s)	Field(s)	Priority	Reviewer Role(s)	Programmatic Review Frequency	Manual Revi
1	If AE Action Taken is drug withdrawn, ou...	In Progress	Clinical.AE		Clinical.AE.AEACN	High	Data Manager, Medical Data Reviewer	Weekly - Sundays @ 14:15	Weekly - Sur
2	AE Serious response is Yes, 'Results in D...	Complete	Clinical.AE		Clinical.AE.AEOUT, Clinic...	Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sur
3	Review AE Term, CTCAE Grade, Start Dat...	Complete	Clinical.AE		Clinical.AE.AEENDAT, Clin...	Medium	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 11:50	Weekly - Mo
4	Review Adverse Event verbatim term to e...	Not Started	Clinical.AE		Clinical.AE.AETERM	High	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 00:00	Weekly - Mo
5	1. Ensure there is no AE, Conmed, Conm...	Complete	Clinical.AE	Clinical.CM		Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sur
6	If Other Action Taken = Concomitant Me...	Not Started	Clinical.AE	Clinical.CM	Clinical.AE.AEACN, Clinic...	High	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 00:00	Weekly - Mo



Review Plan Panel

Data Central | Clintek-010 | Data Central | Workspace Default

0003-001 | Review Objectives 12

Identifier	Review Objective	Status	Primary Domain	Secondary Domain(s)	Field(s)	Priority	Reviewer Role(s)	Programmatic Review Frequency	Manual Review
1	If AE Action Taken is drug withdrawn, ou...	In Progress	Clinical.AE		Clinical.AE.AEACN	High	Data Manager, Medical Data Reviewer	Weekly - Sundays @ 14:15	Weekly - Sunda
2	AE Serious response is Yes, Results in D...	Complete	Clinical.AE		Clinical.AE.AEOUT, Clinic...	Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sunda
3	Review AE Term, CTCAE Grade, Start Dat...	Complete	Clinical.AE		Clinical.AE.AEENDAT, Clin...	Medium	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 11:50	Weekly - Monde
4	Review Adverse Event verbatim term to e...	Not Started	Clinical.AE		Clinical.AE.AETERM	High	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 00:00	Weekly - Monde
5	1. Ensure there is no AE, Conmed, Conm...	Complete	Clinical.AE	Clinical.CM		Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sunda
6	If Other Action Taken = Concomitant Me...	Not Started	Clinical.AE	Clinical.CM	Clinical.AE.AEACN, Clinic...	High	Data Manager, Medical Data Reviewer	Weekly - Mondays @ 00:00	Weekly - Monde
7	If Ongoing is checked and Resolution da...	Not Started	Clinical.MH		Clinical.MH.MHONGO	Medium	Data Manager, Medical Data Reviewer	Daily - @ 16:16	Weekly - Tuesd
8	Random one with all review materials wi...	In Progress	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinical.AE.AEACN, Clinic...	High	Data Manager, Medical Data Reviewe...	Weekly - Sundays @ 16:20	Weekly - Tuesd
9	1. Ensure there is no AE, Conmed, Conm...	In Progress	Clinical.CM	Clinical.AE, Clinical.CM, C...		Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sunda
10	Ensure there is no visit dates, conmeds, ...	Not Started	Clinical.AE	Clinical.CM, Clinical.DS	Clinical.AE.AEONGO	Medium	Data Manager	Weekly - Sundays @ 14:15	Weekly - Sunda
11	Random one with all review materials wi...	In Progress	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinical.AE.AEACN, Clinic...	High	Data Manager, Medical Data Reviewe...	Weekly - Sundays @ 14:15	Weekly - Sunda
12	Review objective with no programmatic ...	Not Started	Clinical.DM			Low	Data Manager, Medical Data Reviewer	On Data Refresh	Weekly - Tuesd



Review Plan Details

Data Central
Clintek-010
Data Central
Workspace Default

0003-001

Study Status

Subjects: 380 / 380

Queries: 0 / 0

Issues: 37 / 904

Review Plan: 3 / 9

Data Exploration

Protocol Deviations

Visualizations

Data

Review Objectives 12

Identifier	Review Objective	Status	Primary Domain	Secondary Domain(s)	Field(s)
1	If AE Action Taken is drug withdrawn, ou...	In Progress	Clinical.AE		Clinic
2	AE Serious response is Yes, Results in D...	Complete	Clinical.AE		Clinic
3	Review AE Term, CTCAE Grade, Start Dat...	Complete	Clinical.AE		Clinic
4	Review Adverse Event verbatim term to e...	Not Started	Clinical.AE		Clinic
5	1. Ensure there is no AE, Conmed, Conm...	Complete	Clinical.AE	Clinical.CM	
6	If Other Action Taken = Concomitant Me...	Not Started	Clinical.AE	Clinical.CM	Clinic
7	If Ongoing is checked and Resolution da...	Not Started	Clinical.MH		Clinic
8	Random one with all review materials wi...	In Progress	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinic
9	1. Ensure there is no AE, Conmed, Conm...	In Progress	Clinical.CM	Clinical.AE, Clinical.CM, C...	Clinic
10	Ensure there is no visit dates, conmeds, ...	Not Started	Clinical.AE	Clinical.CM, Clinical.DS	Clinic
11	Random one with all review materials wi...	In Progress	Clinical.CM	Clinical.AE, Clinical.DM, C...	Clinic
12	Review objective with no programmatic ...	Not Started	Clinical.DM		

Objective: 1

Field(s)	Value(s)
Identifier	1
Review Objective	If AE Action Taken is drug withdrawn, output AE and ENDOSE discontinuation reason RISK STATEMENT:
Status	In Progress
Status Calculated On	27 Jul 2025 14:15:06
Primary Domain	Clinical.AE
Fields	Clinical.AE.AEACN
Priority	High
Reviewer Roles	Data Manager Medical Data Reviewer
Programmatic Review Frequency	Weekly - Sundays @ 14:15
Manual Review Frequency	Weekly - Sundays @ 14:15
Data Central Listings	Clinical.AE Clinical.AEYN Clinical.BMA
App Sheets	CDA - Adverse Event Comparison CDA - Adverse Event Summary CDA - Adverse Events Bubble CDA - Adverse Events Cross Tabulation CDA - Adverse Events Duration CDA - Adverse Events Overlay Labs CDA - AE/Prior and Concomitant Treatment Association CDA - Med Hist, AE and Prior and Concom Treatment
RBQM Dashboard	KRIs
Additional Instructions	Focus on reviewing the manual review materials first, then the programmatic.

Default
Review Plan Details



Key Points of IDRPs

- Review Objectives are aligned to your role.
- You can view Review Objectives assigned to other roles, but can only review based on your role
- Review Objectives are grouped by the Primary Domain (selected during configuration)



Let's jump in...





Thank you

