

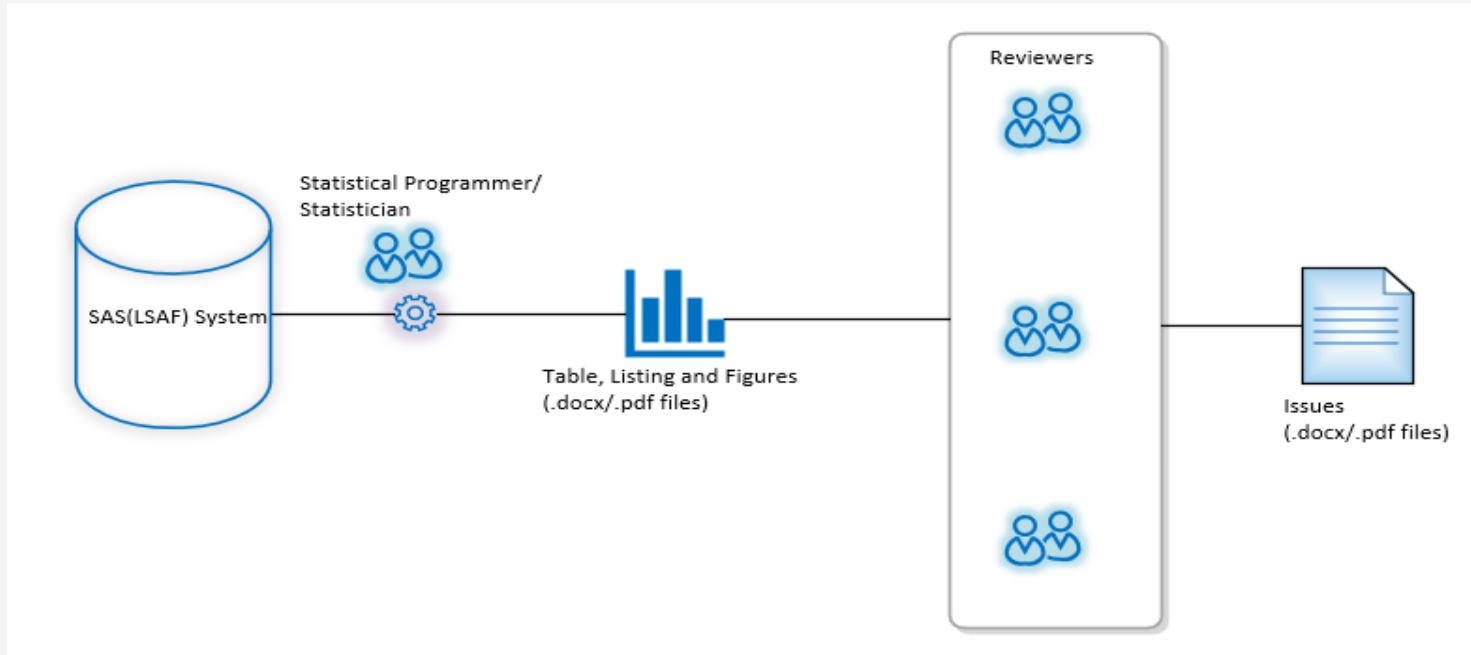
Feedback Modules in Shiny

Introduction of feedback/commenting module in shiny for review..



Traditional Setup1

SAS/LSAF generated outputs(TLF's) in RTF/PDF document.



Pros :

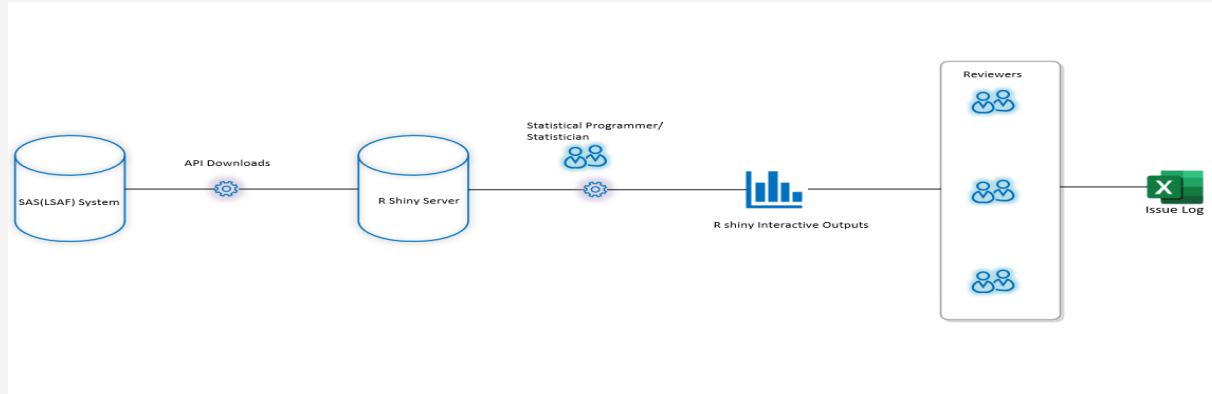
- Easier to log comments.

Cons :

- Difficult to review due to large number of pages and non-interactive.
- No consolidated view of issue logs.
- Difficult to track the issue closures.

Traditional Setup2:

Interactive Outputs/Reviews : R Shiny application.



Pros :

- Easy to review.

Cons :

- Difficult to log comments within the application.
- No consolidated view of issue logs.
- Discussions and resolutions often lost in emails and excels due to lack of central comment logging.
- Repetitive/Duplication review comments for the same data issue by multiple team members. Due to lack of comment visibility.
- Review is performed in a different tool and the issues are logged in a separate tool (e.g. Excel).

Vision:

- Introduction of centralized commenting module.
- Combining data, issue logs and their resolution status in one application.
- Establish efficient review process. Team members have the common understanding of the issues.

Commenting Module Demonstration 1 :

localhost:36511

Data Explorer
Tool for efficient data exploration

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Snapshot Time : February 2025

Demographics Adverse Events Concomitant Medications

Show 20 entries

Search:

View Comment

Submit General Comments :
Write your general comments here...
Submit View Comment

Active Filter Summary

Data Name	Obs
adsl	47/47
adverse_event	466/466
conmed	47/47

Navigation Pane

USUBJID	WEIGHT	HEIGHT	BMI	RACE	RANFL	SAFFL	TRT01P	TRTSDT	EOSSTT	EOSDT	DCSREAS	COMMENT	CRITICAL	STATUS	Buttons
XXXX-SA104-004	79.8	170	27.61	WHITE	Y	Y	PLACEBO	2012-06-04	COMPLETED	2013-06-10					 
XXXX-SA104-005	68	160	26.56	WHITE	Y	Y	DRUG A	2012-06-25	DISCONTINUED	2012-12-24	Lack Of Efficacy				 
XXXX-SA105-008	76	153	32.47	WHITE	Y	N	DRUG A	2012-03-04	COMPLETED	2013-03-02					 
XXXX-SA105-010	94	180	29.01	WHITE	Y	N	DRUG A	2012-04-29	COMPLETED	2013-04-27					 
XXXX-SA105-012	85	178	22.49	WHITE	Y	Y	PLACEBO	2012-06-10	COMPLETED	2013-06-07					 
XXXX-SA105-014	90	184	26.58	WHITE	Y	Y	PLACEBO	2012-06-29	COMPLETED	2013-06-21					 
XXXX-SA105-016	86	182	25.96	WHITE	Y	Y	DRUG A	2012-07-02	COMPLETED	2013-06-23					 
XXXX-SA105-017	72	160	28.12	WHITE	Y	Y	DRUG A	2012-07-28	COMPLETED	2013-07-26					 
XXXX-SA105-018	105	175	34.29		Y	Y	DRUG A	2012-07-29	COMPLETED	2013-07-26					 
XXXX-SA105-019	97	168	34.37	WHITE	Y	Y	PLACEBO	2012-07-29	COMPLETED	2013-07-28					 
XXXX-SA105-021	68	162	25.91	WHITE	Y	Y	PLACEBO	2012-08-03	COMPLETED	2013-08-04					 
XXXX-SA105-022	90	172	30.42	WHITE	Y	Y	DRUG A	2012-08-03	COMPLETED	2013-07-28					 
XXXX-US101-001	60.3	160	23.55	WHITE	Y	Y	DRUG A	2012-05-05	COMPLETED	2013-05-24					 
XXXX-US102-001	640	154	35.42	WHITE	Y	Y	PLACEBO	2012-01-03	COMPLETED	2012-12-31					 
XXXX-US102-002	114.4	182.5	34.35	WHITE	Y	Y	DRUG A	2012-01-04	COMPLETED	2013-01-02					 
XXXX-US102-003	93.5	165	34.34	BLACK OR AFRICAN AMERICAN	Y	Y	DRUG A	2012-01-15	COMPLETED	2013-01-25					 

Add Comment

Filter Pane

Active Filter Variables + - x

adsl	0 filters applied
adverse_event	0 filters applied
conmed	0 filters applied

General Comment Section

Commenting Module Demonstration 2 : Adding comment

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Demographics Adverse Events Concomitant Medications

Show 20 entries

USUBJID	WEIGHT	HEIGHT	BMI	RACE	SEX
XXXX-SA104-004	79.8	170	27.61	WHITE	Y
XXXX-SA104-005	68	160	26.56	WHITE	Y
XXXX-SA105-008	76	153	32.47	WHITE	Y
XXXX-SA105-010	94	180	29.01	WHITE	Y
XXXX-SA105-012	65	170	22.49	WHITE	Y
XXXX-SA105-014	90	184	26.58	WHITE	Y
XXXX-SA105-016	86	182	25.96	WHITE	Y
XXXX-SA105-017	72	160	28.12	WHITE	Y
XXXX-SA105-018	105	175	34.29		Y
XXXX-SA105-019	97	168	34.37	WHITE	Y
XXXX-SA105-021	68	162	25.91	WHITE	Y
XXXX-SA105-022	90	172	30.42	WHITE	Y
XXXX-US101-001	60.3	160	23.55	WHITE	Y
XXXX-US102-001	640	154	35.42	WHITE	Y
XXXX-US102-002	114.4	182.5	34.35	WHITE	Y
XXXX-US102-003	93.5	165	34.34	BLACK OR AFRICAN AMERICAN	Y
XXXX-US102-004	120	175.2	39.09		Y
XXXX-US102-007	80.5	175.2	26.23	BLACK OR AFRICAN AMERICAN	Y
XXXX-US102-008	84.5	151.2	36.96	BLACK OR AFRICAN AMERICAN	Y
XXXX-US102-009	126	180.7	38.59	WHITE	Y

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Submit General Comments :

Write your general comments here...

Submit View Comment

Search:

COMMENT CRITICAL STATUS Buttons

Filter Summary

Data Name	Obs
adsl	47/47
adverse_event	466/466
conmed	47/47

Active Filter Variables + - ⊗
adsl
0 filters applied
adverse_event
0 filters applied
conmed
0 filters applied

Add Filter Variables
Add adsl filter
Select variable to filter
Add adverse_event filter

Add Comment :

Subject Identifier
XXXX-US102-001

PREVIOUS COMMENTS

COMMENT
Weight is entered as 640. Seems to be data issue. Kindly check.

CRITICAL
High

STATUS
Open

Submit Edits Close

New Comments

Commenting Module Demonstration 3 :Archiving comment

The screenshot displays the 'Data Explorer' application interface. A modal window titled 'Add Comment :' is open, showing a 'Subject Identifier' field with the value 'XXXX-US102-001'. Below this, a 'PREVIOUS COMMENTS' section contains a comment from 'Reviewer1 (26Feb2025) : Weight is entered as 640. Seems to be data issue. Kindly check.' A 'COMMENT' text area is empty. At the bottom of the modal, there are 'CRITICAL' and 'STATUS' dropdown menus, currently set to 'High' and 'Open' respectively, and 'Submit Edits' and 'Close' buttons.

In the background, the 'Data Explorer' interface is visible, showing a table of data with columns like 'USUBJID', 'WEIGHT', 'HEIGHT', 'BMI', 'RACE', etc. A red box highlights the 'Archived Comments' section, which is a table with columns 'COMMENT', 'CRITICAL', 'STATUS', and 'Buttons'. The table contains one row with the comment 'Reviewer1 (26Feb2025) : Weight is entered as 640. Seems to be data issue. Kindly check.', 'High', 'Open', and edit/delete icons.

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Search:

Write your general comments here...

Submit View Comment

Active Filter Summary

Data Name	Obs
adsl	47/47
adverse_event	466/466
conmed	47/47

Active Filter Variables + -

adsl
0 filters applied

adverse_event
0 filters applied

conmed
0 filters applied

Add Filter Variables

Add adsl filter

Select variable to filter

Add adverse_event filter

Commenting Module Demonstration 4 :Adding comment by multiple reviewer/ responder

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Demographics

Adverse Events

Concomitant Medication

Show

20

entries

USUBJID	WEIGHT	HEIGHT	BMI	RACE	SEX
XXXX-SA104-004	79.8	170	27.61	WHITE	Y
XXXX-SA104-005	68	160	26.56	WHITE	Y
XXXX-SA105-008	76	153	32.47	WHITE	Y
XXXX-SA105-010	94	180	29.01	WHITE	Y
XXXX-SA105-012	65	170	22.49	WHITE	Y
XXXX-SA105-014	90	184	26.58	WHITE	Y
XXXX-SA105-016	86	182	25.96	WHITE	Y
XXXX-SA105-017	72	160	28.12	WHITE	Y
XXXX-SA105-018	105	175	34.29		Y
XXXX-SA105-019	97	168	34.37	WHITE	Y
XXXX-SA105-021	68	162	25.91	WHITE	Y
XXXX-SA105-022	90	172	30.42	WHITE	Y
XXXX-US101-001	60.3	160	23.55	WHITE	Y

XXXX-US102-001

640

154

35.42

WHITE

Y

Y

PLACEBO

2012-01-03

COMPLETED

2012-12-31

Reviewer1 (26Feb2025) : Weight is entered as 640. Seems to be data issue. Kindly check.

High

Open

✎

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XXXX-US102-002

114.4

182.5

34.35

WHITE

Y

Y

DRUG A

2012-01-04

COMPLETED

2013-01-02

✎

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XXXX-US102-003	93.5	165	34.34	BLACK OR AFRICAN AMERICAN	Y	Y	DRUG A	2012-01-15	COMPLETED	2013-01-25			✎ 🔒
XXXX-US102-004	120	175.2	39.09		Y	Y	PLACEBO	2012-02-08	COMPLETED	2013-02-05			✎ 🔒
XXXX-US102-007	80.5	175.2	26.23	BLACK OR AFRICAN AMERICAN	Y	Y	DRUG A	2012-03-07	DISCONTINUED	2012-10-19	Withdrawal Of Consent		✎ 🔒

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Submit General Comments :

Write your general comments here...

Submit

View Comment

Active Filter Summary

Data Name

Obs

adsl

47/47

adverse_event

466/466

conmed

47/47

Active Filter Variables

adsl

0 filters applied

adverse_event

0 filters applied

conmed

0 filters applied

Add Filter Variables

Add adsl filter

Select variable to filter

Add adverse_event filter

Add Comment :

Subject Identifier

XXXX-US102-001

PREVIOUS COMMENTS

Reviewer1 (26Feb2025) : Weight is entered as 640. Seems to be data issue. Kindly check.

COMMENT

Query Raised.

CRITICAL

High

STATUS

Closed

Submit Edits

Close

Commenting Module Demonstration 5 : Archiving multiple comments

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Snapshot Time : February2025

Demographics

Adverse Events

Concomitant Medications

Show

20

entries

USUBJID	WEIGHT	HEIGHT	BMI	RACE	SEX
XXXX-SA104-004	79.8	170	27.61	WHITE	Y
XXXX-SA104-005	68	160	26.56	WHITE	Y
XXXX-SA105-008	76	153	32.47	WHITE	Y
XXXX-SA105-010	94	180	29.01	WHITE	Y
XXXX-SA105-012	65	170	22.49	WHITE	Y
XXXX-SA105-014	90	184	26.58	WHITE	Y
XXXX-SA105-016	86	182	25.96	WHITE	Y
XXXX-SA105-017	72	160	28.12	WHITE	Y
XXXX-SA105-018	105	175	34.29		Y
XXXX-SA105-019	97	168	34.37	WHITE	Y
XXXX-SA105-021	68	162	25.91	WHITE	Y
XXXX-SA105-022	90	172	30.42	WHITE	Y
XXXX-US101-001	60.3	160	23.55	WHITE	Y

XXXX-US102-001

640

154

35.42

WHITE

Y

Y

PLACEBO

2012-01-03

COMPLETED

2012-12-31

Reviewer1 (26Feb2025) : Weight is entered as 640. Seems to be data issue. Kindly check. DM (28Feb2025) : Query Raised.

High

Closed

📝

👁

XXXX-US102-002

114.4

182.5

34.35

WHITE

Y

Y

DRUG A

2012-01-04

COMPLETED

2013-01-02

📝

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XXXX-US102-003	93.5	165	34.34	BLACK OR AFRICAN AMERICAN	Y	Y	DRUG A	2012-01-15	COMPLETED	2013-01-25			📝 👁
XXXX-US102-004	120	175.2	39.09		Y	Y	PLACEBO	2012-02-08	COMPLETED	2013-02-05			📝 👁
XXXX-US102-007	80.5	175.2	26.23	BLACK OR AFRICAN	Y	Y	DRUG A	2012-03-07	DISCONTINUED	2012-10-19	Withdrawal Of		📝 👁

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Submit General Comments :

Write your general comments here...

Submit

View Comment

Active Filter Summary

Data Name	Obs
adsl	47/47
adverse_event	466/466
conmed	47/47

Active Filter Variables

adsl

0 filters applied

adverse_event

0 filters applied

conmed

0 filters applied

Add Filter Variables

Add **adsl** filter

Select variable to filter

Add **adverse_event** filter

GRÜNENTHAL

Commenting Module Demonstration 6 : Adding General / common comments applicable across listings

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Snapshot Time : February2025

Demographics Adverse Events Concomitant Medications

Show 20 entries Search:

USUBJID	WEIGHT	HEIGHT	BMI	RACE	RANDFL	SAFFL	TRT01P	TRTSDT	EOSSTT	EOSDT	DCSREAS	COMMENT	CRITICAL	STATUS	Buttons
XXXX-SA104-004	79.8	170	27.61	WHITE	Y	Y	PLACEBO	2012-06-04	COMPLETED	2013-06-10					 
XXXX-SA104-005	68	160	26.56	WHITE	Y	Y	DRUG A	2012-06-25	DISCONTINUED	2012-12-24	Lack Of Efficacy				 
XXXX-SA105-008	76	153	32.47	WHITE	Y	N	DRUG A	2012-03-04	COMPLETED	2013-03-02		Reviewer1(26Feb2025) : Subject has completed the study but safety flag is N? Reviewer2(28Feb2025): Kindly confirm if the reason is related to randomization by mistake?	High	Open	 
XXXX-SA105-010	94	180	29.01	WHITE	Y	N	DRUG A	2012-04-29	COMPLETED	2013-04-27					 
XXXX-SA105-012	65	170	22.49	WHITE	Y	Y	PLACEBO	2012-06-10	COMPLETED	2013-06-07					 
XXXX-SA105-014	90	184	26.58	WHITE	Y	Y	PLACEBO	2012-06-29	COMPLETED	2013-06-21					 
XXXX-SA105-016	86	182	25.96	WHITE	Y	Y	DRUG A	2012-07-02	COMPLETED	2013-06-23					 
XXXX-SA105-017	72	160	28.12	WHITE	Y	Y	DRUG A	2012-07-28	COMPLETED	2013-07-26					 
XXXX-SA105-018	105	175	34.29		Y	Y	DRUG A	2012-07-29	COMPLETED	2013-07-26		Reviewer1(25Feb2025): Race is missing for this subject. Seems to be data issue. Kindly check. DM(28Feb2025) : Query Raised.	High	Closed	 
XXXX-SA105-019	97	168	34.37	WHITE	Y	Y	PLACEBO	2012-07-29	COMPLETED	2013-07-28					 
XXXX-SA105-															 

Submit General Comments :

Reviewer1: Treatment End dates need to be added in the listings.

[Submit](#) [View Comment](#)

Active Filter Summary

Data Name	Obs
adsl	47/47
adverse_event	466/466
conmed	47/47

Active Filter Variables + - x

adsl 0 filters applied

adverse_event 0 filters applied

conmed 0 filters applied

Add Filter Variables

Add **adsl** filter

Select variable to filter

Add **adverse_event** filter

General
Comments
Section

Commenting Module Demonstration 7 : Adding comments for Table

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DemographicsAdverse EventsConcomitant Medications

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Sex				
n	133	134	132	399
F	79 (59%)	82 (61.2%)	70 (53%)	231 (57.8%)
M	54 (40.3%)	52 (38.8%)	62 (47%)	168 (42%)
Race				
n	134	134	132	400
ASIAN	68 (50.7%)	67 (50%)	73 (55.3%)	208 (52%)
BLACK OR AFRICAN AMERICAN	31 (23.1%)	28 (20.9%)	32 (24.2%)	91 (22.8%)
WHITE	27 (20.1%)	26 (19.4%)	21 (15.9%)	74 (18.5%)
AMERICAN INDIAN OR ALASKA NATIVE	8 (6%)	11 (8.2%)	6 (4.5%)	25 (6.2%)
MULTIPLE	0	1 (0.7%)	0	1 (0.2%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1 (0.7%)	0	1 (0.2%)
OTHER	0	0	0	0
UNKNOWN	0	0	0	0
Reason for Discontinuation from Study				
n	42	40	38	120
ADVERSE EVENT	3 (2.2%)	6 (4.5%)	5 (3.8%)	14 (3.5%)
DEATH	25 (18.7%)	23 (17.2%)	22 (16.7%)	70 (17.5%)
LACK OF EFFICACY	2 (1.5%)	2 (1.5%)	3 (2.3%)	7 (1.8%)

Submit General Comments :

Reviewer1 (26Feb2025) : Count of SEX for Drug X is not consistent with population count. Kindly check.

SubmitView Comment

Active Filter Summary

Data Name	Obs
adsl	400/400
adverse_event	466/466
conmed	47/47

Active Filter Variables

adsl +adverse_event +conmed +

General
Comments
Section

Commenting Module Demonstration 8 : Pulling consolidated comments in one application

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Search:

	WEIGHT	HEIGHT	RACE	RANDFL	SAFFL	TRT01P	TRTSDT	EOSSTT	EOSDT	DCSREAS	COMMENT	CRITICAL	STATUS	Buttons
XXXX-SA104-005	68	160	26.56 WHITE	Y	Y	PLACEBO	2012-06-04	COMPLETED	2013-06-10					
XXXX-SA105-008	76	153	32.47 WHITE	Y	Y	DRUG A	2012-06-25	DISCONTINUED	2012-12-24	Lack Of Efficacy	Reviewer1 (26Feb2025) : Subject has completed the study but safety flag is N?			
XXXX-SA105-010	94	180	29.01 WHITE	Y	N	DRUG A	2012-04-29	COMPLETED	2013-04-27					
XXXX-SA105-012	65	170	22.49 WHITE	Y	Y	PLACEBO	2012-06-10	COMPLETED	2013-06-07					
XXXX-SA105-014	90	184	26.58 WHITE	Y	Y	PLACEBO	2012-06-29	COMPLETED	2013-06-21					
XXXX-SA105-016	86	182	25.96 WHITE	Y	Y	DRUG A	2012-07-02	COMPLETED	2013-06-23					
XXXX-SA105-017	72	160	28.12 WHITE	Y	Y	DRUG A	2012-07-28	COMPLETED	2013-07-26					
XXXX-SA105-018	105	175	34.29	Y	Y	DRUG A	2012-07-29	COMPLETED	2013-07-26		Reviewer1 (25Feb2025): Race is missing for this subject. Seems to be data issue. Kindly check. DM (28Feb2025) : Query Raised.			
XXXX-SA105-019	97	168	34.37 WHITE	Y	Y	PLACEBO	2012-07-29	COMPLETED	2013-07-28					

Consolidated Comments pull

Submit General Comments :

Write your general comments here...

Submit View Comment

Active Filter Summary

Data Name	Obs
adsl	47/47
adverse_event	466/466
conmed	47/47

Active Filter Variables

- adsl 0 filters applied
- adverse_event 0 filters applied
- conmed 0 filters applied

Add Filter Variables

Add adsl filter

Select variable to filter

Add adverse_event filter

Commenting Module Demonstration 9 : Example of comments consolidated in an excel

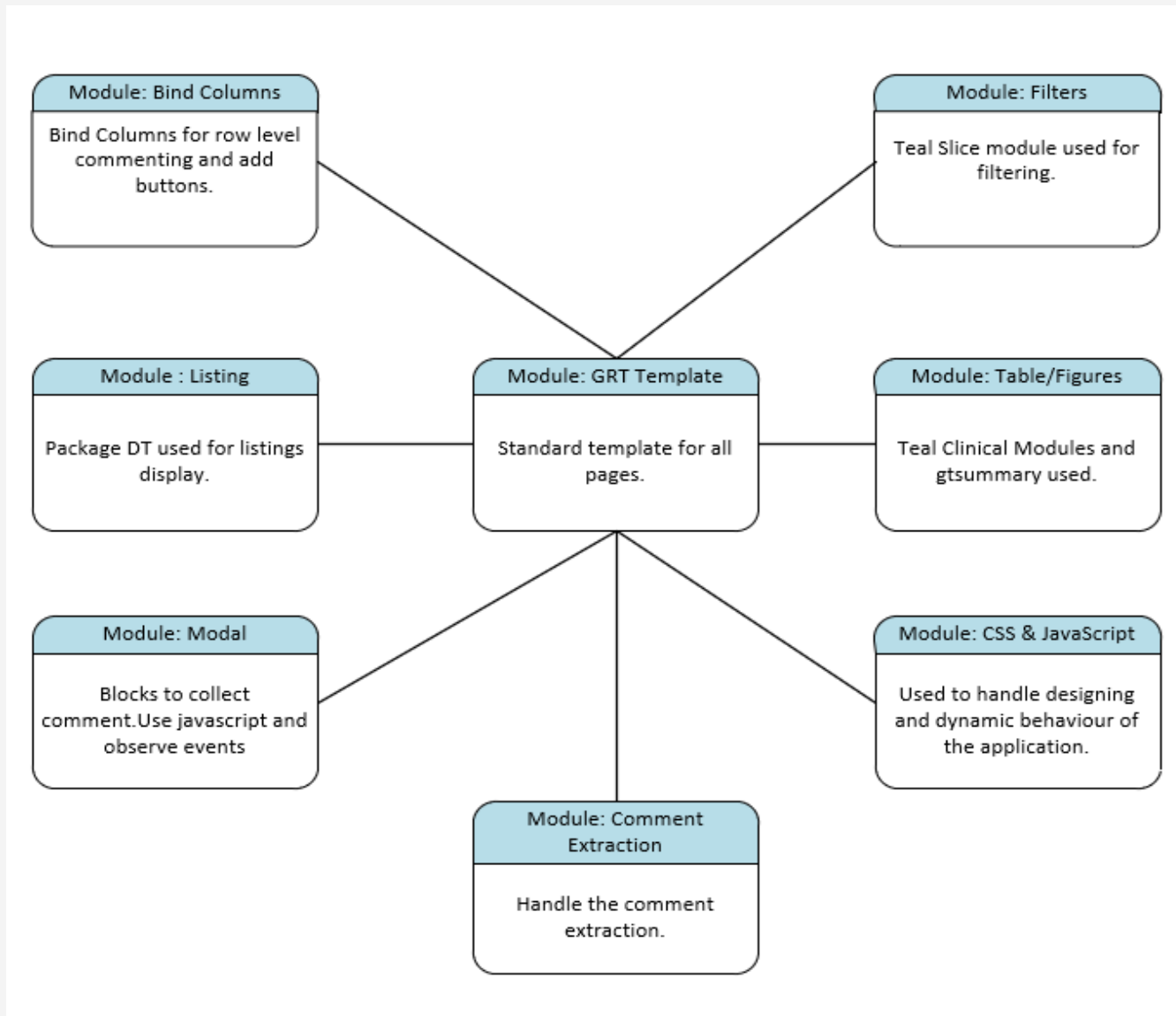
Excel interface showing a spreadsheet titled "Cumulative comments_listings.xlsx". The ribbon includes File, Home, Insert, Page Layout, Formulas, Data, Review, View, Automate, Help, and GRT Tools. The Home ribbon is active, showing options for Clipboard, Font, Alignment, Number, and Styles.

The spreadsheet displays a table with the following columns: Reviewer, Date, Subject Identifier, COMMENT, CRITICAL, and STATUS. The data is as follows:

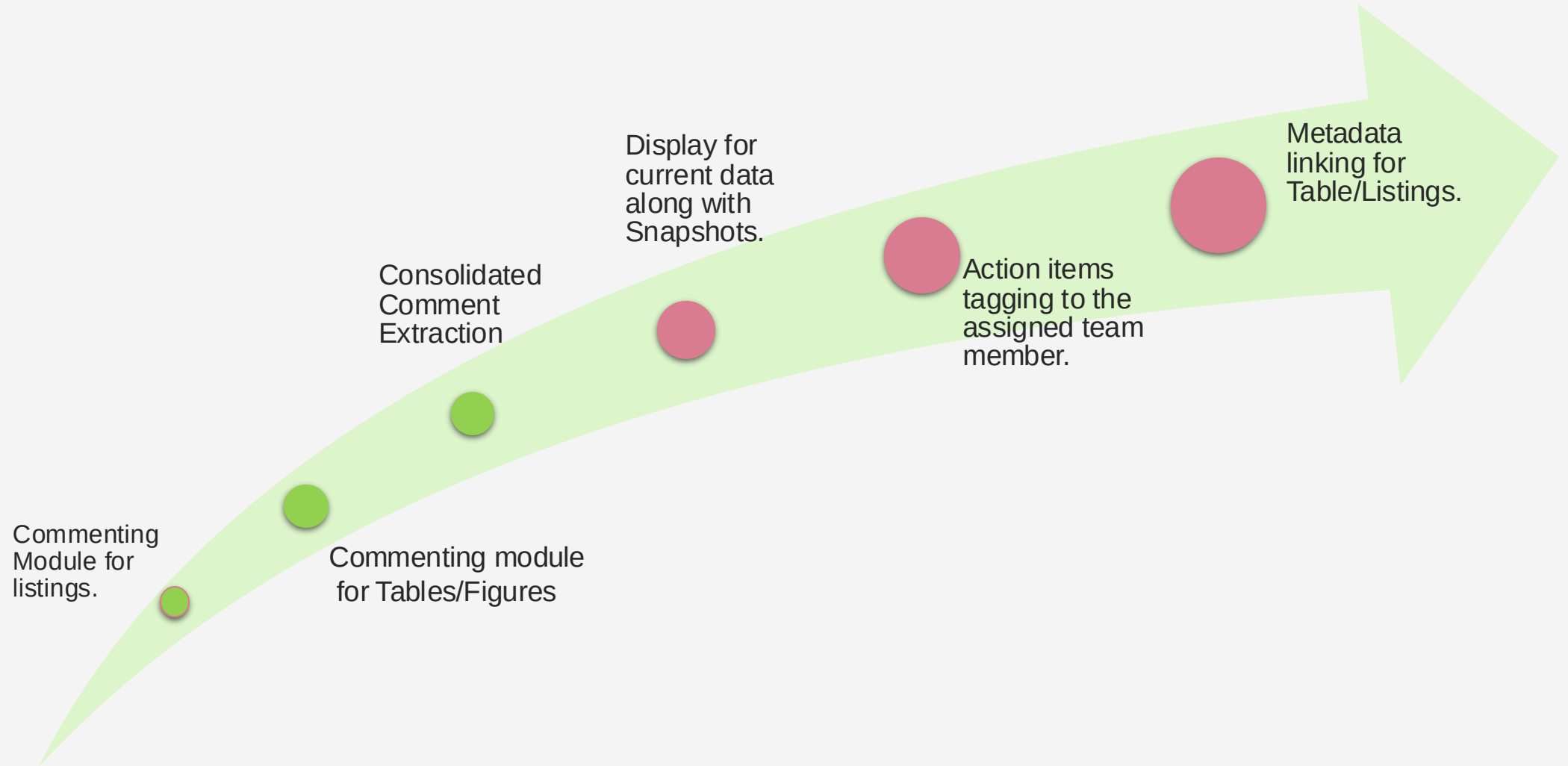
Reviewer	Date	Subject Identifier	COMMENT	CRITICAL	STATUS
Reviewer1	26-Feb-25	XXX-US102-001	Weight Is entered as 640. Seems to be data issue. Kindly check.	High	Closed
DM	28-Feb-25	XXX-US102-001	Query Raised	High	Closed
Reviewer1	26-Feb-25	XXX-SA105-008	Subject has completed the study but safety flag is N?	High	Open
Reviewer2	28-Feb-25	XXX-SA105-008	Kindly confirm if the reason is related to randomization by mistake?	High	Open
Reviewer1	25-Feb-25	XXX-SA105-018	Race Is missing for this subject. Seems to be data issue. Kindly check.	High	Closed
DM	28-Feb-25	XXX-SA105-018	Query Raised	High	Closed

The bottom of the interface shows a tab labeled "Demographics" selected, with other tabs visible: "Advere Events" and "Concomitant Medications".

Application Modules:



Roadmap :



Thank You

Questions?