



Insider Client Training Session: elluminate Assist

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March 6, 2025



Agenda

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Overview of
elluminate Assist

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Configuration of
elluminate Assist

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Using elluminate
Assist in Data
Central

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Questions





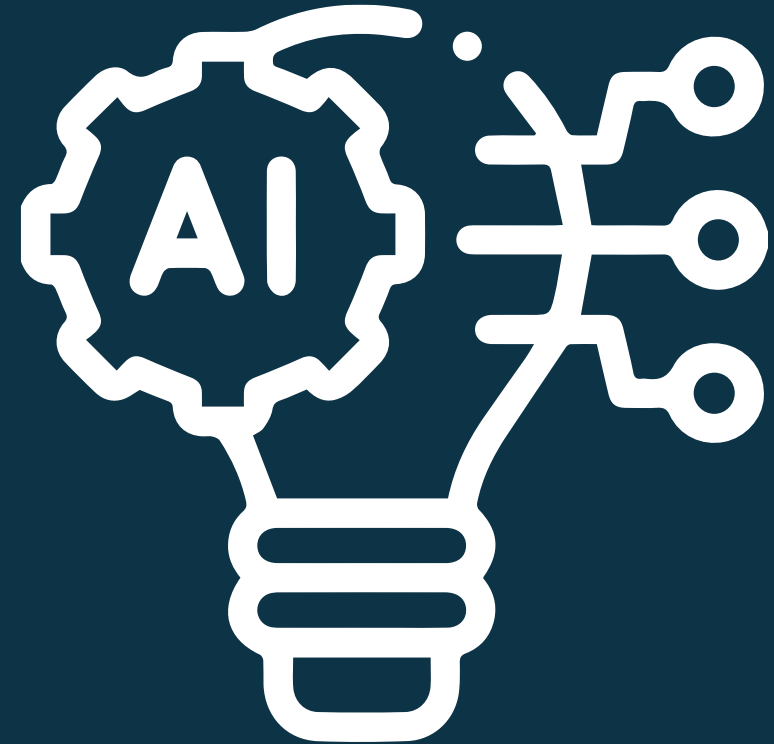
illuminate Assist Overview



What is illuminate Assist?

illuminate Assist...

- Is a **Gen-AI chatbot** designed to help you understand and analyze your **SDTM** clinical trial data.
- Provides answers to your questions in plain English and **generates SQL queries** to support verification and further analysis.
- Uses a model that **understands SDTM data** and the **relationships** across different domain.



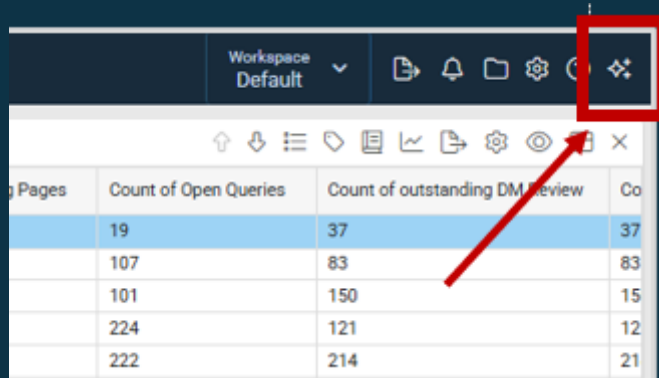
Currently available for the following SDTM domains: AE, CM, DM, DS, EG, EX, LB, MH, PR, SV, VS



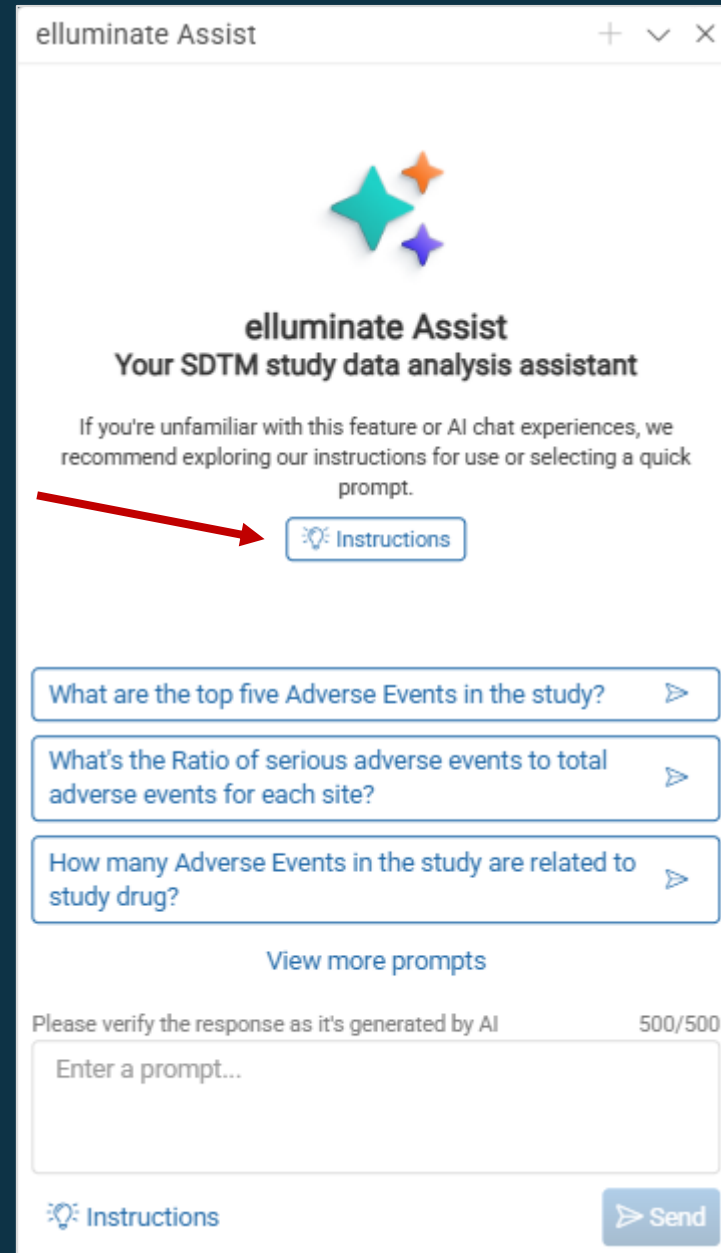
Before Using illuminate Assist

We recommend that you review the **Instructions** in the chatbot to:

- Read General information and the Disclaimer
- Review Tips for effective use
- See the list of available Quick Prompts



Pages	Count of Open Queries	Count of outstanding DM Review	Co
19	37	37	37
107	83	83	83
101	150	15	15
224	121	12	12
222	214	21	21



illuminate Assist

illuminate Assist
Your SDTM study data analysis assistant

If you're unfamiliar with this feature or AI chat experiences, we recommend exploring our instructions for use or selecting a quick prompt.

[Instructions](#)

What are the top five Adverse Events in the study?

What's the Ratio of serious adverse events to total adverse events for each site?

How many Adverse Events in the study are related to study drug?

[View more prompts](#)

Please verify the response as it's generated by AI 500/500

Enter a prompt...

[Instructions](#) [Send](#)



Instruction Information

elluminate Assist + - x

[Close Instructions](#)

Instructions

About Tips Quick Prompts

About elluminate Assist

Please read this disclaimer carefully before engaging with the elluminate Assist provided by elluminate@. By accessing and using elluminate Assist, you acknowledge and agree to the terms of this disclaimer.

1. General Information: elluminate Assist is designed to provide general information and guidance related to information available in elluminate@. While elluminate Assist strives to provide accurate and helpful information, eCS does not guarantee that the information will be complete, accurate, or up to date. Accordingly, the information provided by elluminate Assist should not be considered legal advice or a substitute for a consultation or discussion with one of eCS' employees. elluminate Assist is an AI program and not an employee of eCS.

2. Liability Disclaimer: Users of elluminate Assist are solely responsible for their interaction and reliance on the information provided. eCS shall not be held liable for any errors or omissions in the information provided by elluminate Assist or for any actions taken or not taken in reliance upon it. eCS expressly disclaims any liability for any direct or indirect damages arising from the use or reliance on elluminate Assist's response or the content provided on this platform.

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Instructions

About **Tips** Quick Prompts

Tips for Effective Use

Access and User-Specific Information

User-Specific Access:
elluminate Assist is accessible only within Data Central, tailored to individual users, allowing access only to authorized data.

Querying and Data Specifications

Frame prompts in the form of a question:
Always frame prompts as questions or direct instructions. For SDTM data queries, direct them to the appropriate safety forms (AE, CM, DM, DS, EX, LB, MH, VS, SV, EG, and PR).

Date Imputation Logic:
elluminate Assist uses the first day of the month if the day is unspecified, and uses January if the month is unspecified.

Ask Clear Questions:
For clarity, break complex queries into simpler, jargon-free components. The elluminate Assist does not have domain knowledge stored outside of the store data.

Ensuring Accuracy

Validate Response Accuracy:
Access the SQL code or logic explanation in each response to validate its accuracy.

Ensure Accuracy in Phrases:
Verify the spelling for specific terms to avoid errors and improve search effectiveness.

Specify Calculation Logic for Derived Variables:
When querying about derived variables like AE duration, provide

elluminate Assist + - x

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Instructions

About Tips **Quick Prompts**

Quick Prompts

What are the top five Adverse Events in the study? >

What's the Ratio of serious adverse events to total adverse events for each site? >

How many Adverse Events in the study are related to study drug? >

Which patients got hospitalized due to an adverse event? For these patients, show the siteid, subjectid, adverse event preferred term, start date of the adverse event, relative study day of start, action taken,hospitalization, and outcome. >

How many subjects experienced severe adverse events and also had high blood pressure readings recorded in the vital signs domain during the study? >

Which subjects have adverse events that have resulted in an action taken of dose reduced? >

How many serious adverse events were reported for this study? Return the breakdown by system organ class and by High Level Term. >

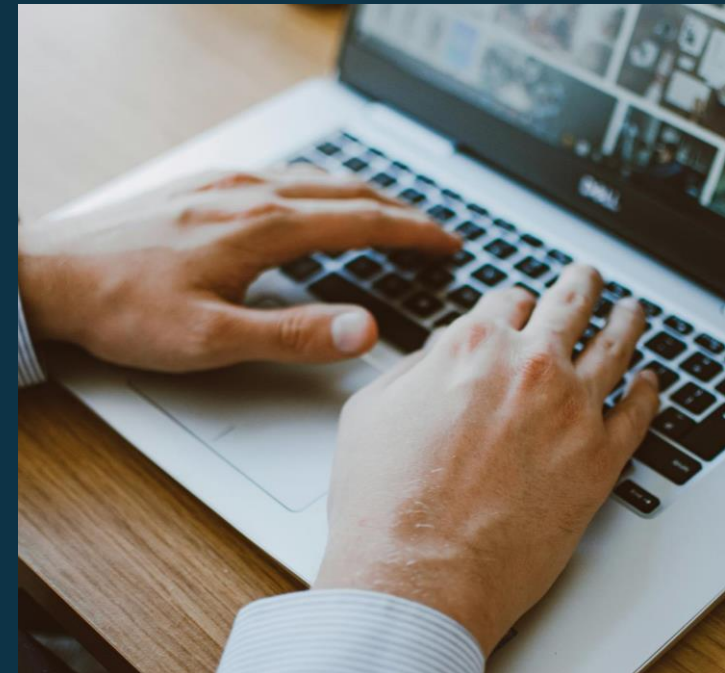
What is the count of serious adverse events in each treatment arm? >



Before Using illuminate Assist

Be aware that 100% accuracy cannot be guaranteed given the nature of generative AI; multiple steps have been taken to promote high accuracy of the responses:

- ✓ Extensive testing with both domain and SQL experts
- ✓ Guardrails in place to ensure that responses are on topic and do not include harmful SQL queries
- ✓ Responses will always include SQL and the query results to ensure the explanation is generated from the data and SDTM relationships



A Few Key Points...

- For Data Exploration; important to validate answers
- Answers are provided based on the data available at the time of the query; previous responses do not update when data are updated
- For highly complex queries, we recommend you break them down to ensure each response and SQL output are properly reviewed
- elluminate Assist can retrieve data elements from specific records and perform statistical analyses such as averages and min max calculations. Also, supports complex joins and aggregations across multiple domains
- If Partial Dates are in the data being retrieved,
 - If the day is missing, defaults to the first day of the month
 - If the month is missing, defaults to January
 - If the year is missing, it will return an error
- elluminate Assist retains the context of previous questions and responses in a conversation, allowing you to ask follow up questions without restating the full initial query
- The 10 most recent chat sessions remain accessible in elluminate Assist for up to 30 days
- Only access to your own chats



Configuration

- Must be turned on at the URL level
- Configured at the Study level
- Currently available within Data Central
- Reporting Data Store is selected by default but can be changed. Must be SDTM data.

Edit Study: eCS-ONCODEMO

Configuration Standards Dictionaries **Settings** ETL Data Blinding

Active

Ongoing Ongoing As Of: 1/28/2022

Blinded Data

Data Central

eIQ Review

elluminate Assist Select SDTM Data Store: Reporting

Protocol Deviations

Risk Based Quality Management (RBQM) & Risk Assessment & Categorization Tool (RACT)





Using illuminate Assist



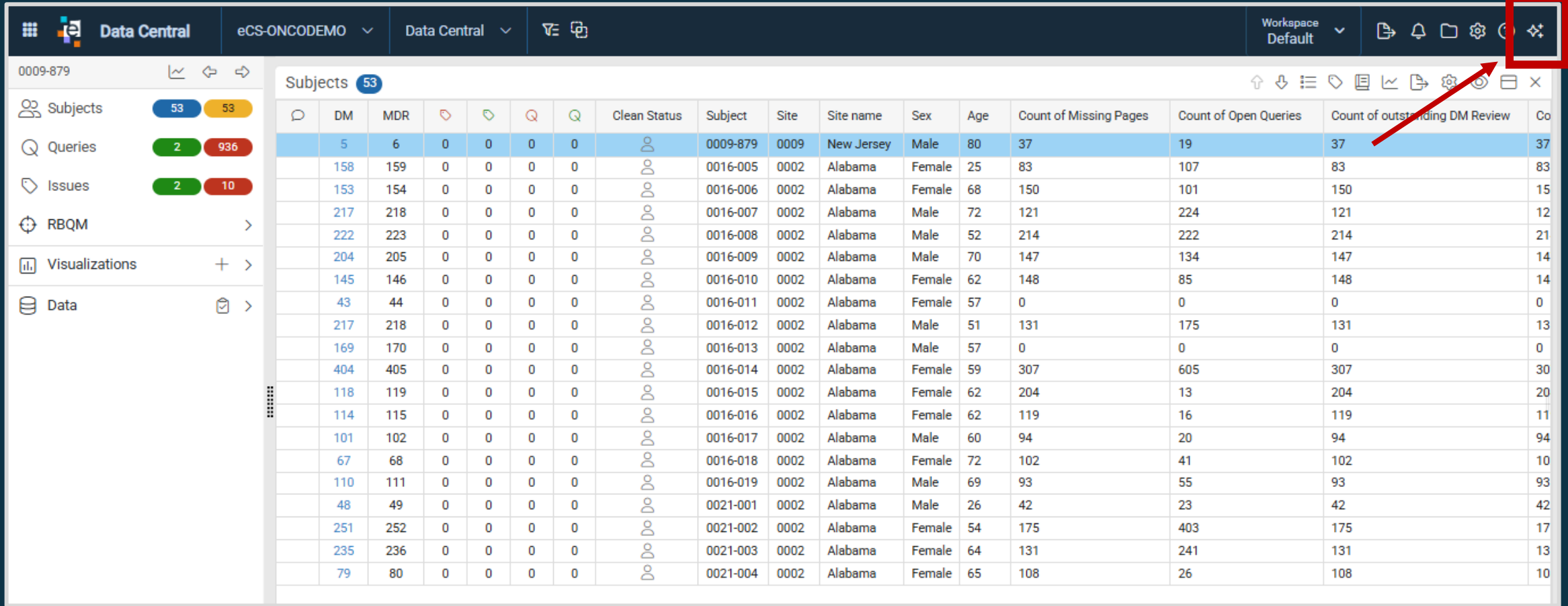
Accessing illuminate Assist

0009-879

Subjects 53

DM	MDR					Clean Status	Subject	Site	Site name	Sex	Age	Count of Missing Pages	Count of Open Queries	Count of outstanding DM Review	Co
5	6	0	0	0	0		0009-879	0009	New Jersey	Male	80	37	19	37	37
158	159	0	0	0	0		0016-005	0002	Alabama	Female	25	83	107	83	83
153	154	0	0	0	0		0016-006	0002	Alabama	Female	68	150	101	150	15
217	218	0	0	0	0		0016-007	0002	Alabama	Male	72	121	224	121	12
222	223	0	0	0	0		0016-008	0002	Alabama	Male	52	214	222	214	21
204	205	0	0	0	0		0016-009	0002	Alabama	Male	70	147	134	147	14
145	146	0	0	0	0		0016-010	0002	Alabama	Female	62	148	85	148	14
43	44	0	0	0	0		0016-011	0002	Alabama	Female	57	0	0	0	0
217	218	0	0	0	0		0016-012	0002	Alabama	Male	51	131	175	131	13
169	170	0	0	0	0		0016-013	0002	Alabama	Male	57	0	0	0	0
404	405	0	0	0	0		0016-014	0002	Alabama	Female	59	307	605	307	30
118	119	0	0	0	0		0016-015	0002	Alabama	Female	62	204	13	204	20
114	115	0	0	0	0		0016-016	0002	Alabama	Female	62	119	16	119	11
101	102	0	0	0	0		0016-017	0002	Alabama	Male	60	94	20	94	94
67	68	0	0	0	0		0016-018	0002	Alabama	Female	72	102	41	102	10
110	111	0	0	0	0		0016-019	0002	Alabama	Male	69	93	55	93	93
48	49	0	0	0	0		0021-001	0002	Alabama	Male	26	42	23	42	42
251	252	0	0	0	0		0021-002	0002	Alabama	Female	54	175	403	175	17
235	236	0	0	0	0		0021-003	0002	Alabama	Female	64	131	241	131	13
79	80	0	0	0	0		0021-004	0002	Alabama	Female	65	108	26	108	10

Workspace Default



Accessing illuminate Assist

Data Central eCS-ONCODEMO Data Central Workspace Default

0009-879

- Subjects 53
- Queries 2 936
- Issues 2 11
- elQ Review
- Visualizations
- Data
 - Clinical
 - CTOA
 - Data Central
 - DCReporting
 - Adverse Events
 - Demographics
 - SeriousAEOngoing
 - Vital Signs
 - Exception Listings
 - Irregular Data Patterns
 - Reconciliation Reports

DM	MDR	Clean Status	Subject	Site	Site name	Sex	Age	Count of Missin
6	6		0009-879	0009	New Jersey	Male	80	37
140	159		0016-005	0002	Alabama	Female	25	83
145	154		0016-006	0002	Alabama	Female	68	150
182	218		0016-007	0002	Alabama	Male	72	121
189	223		0016-008	0002	Alabama	Male	52	214
183	205		0016-009	0002	Alabama	Male	70	147
128	146		0016-010	0002	Alabama	Female	62	148
40	44		0016-011	0002	Alabama	Female	57	0
182	218		0016-012	0002	Alabama	Male	51	131
133	170		0016-013	0002	Alabama	Male	57	0
298	405		0016-014	0002	Alabama	Female	59	307
102	119		0016-015	0002	Alabama	Female	62	204
96	115		0016-016	0002	Alabama	Female	62	119
83	102		0016-017	0002	Alabama	Male	60	94
60	68		0016-018	0002	Alabama	Female	72	102
90	111	1	0016-019	0002	Alabama	Male	69	93
44	49		0021-001	0002	Alabama	Male	26	42
180	252		0021-002	0002	Alabama	Female	54	175
187	236		0021-003	0002	Alabama	Female	64	131
75	80		0021-004	0002	Alabama	Female	65	108
8	10		0021-016	0002	Alabama	Male	34	108
236	299		0021-018	0009	New Jersey	Female	52	178
148	170		0021-019	0009	New Jersey	Female	61	141
151	187		0021-020	0009	New Jersey	Female	68	114
187	231		0021-021	0009	New Jersey	Male	66	152
194	250		0021-022	0009	New Jersey	Female	68	126

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[Instructions](#) [Send](#)



Let's jump in...





Thank you

