DDF CPT CLI Tool User Guidev1.0

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Document History

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Contents

1. Overview 2
2. Prerequisites 2
3. Installation 2
   3.1 Summary of Tool Artifacts 2
   3.2 Summary of Tool Capabilities 3
4. Tool Commands 3
   4.1 Run the Tool 3
   4.2 Get Tool Version 4
   4.3 Get Tool Help 4
   4.4 About command 4
   4.5 Config command 5
   4.6 Study Command 5
      4.6.1 Get Study Data from a File 5
      4.6.2 Get Study Data from the SDR API 6
      4.6.3 Write Study Data to an eCPT Document 6
5. Proof of Concept Scope and Limitations 7
6. Troubleshoot 7
7. Appendix 8
   7.1 Tool Help Example Output 8
   7.2 About Command Example Output 8
   7.3 Config Command Example Output 9
   7.4 Study Command Example Study File Data Output 10
   7.5 Study Command Example Study API Data Output 11
   7.6 Study Command Example eCPT Writing Output 12
   7.7 Study Command Example eCPT Document 13

1. Overview

This is the documentation for the SDRtoCPT proof of concept (PoC).

The SDRtoCPT application is a command line interface (CLI) tool (referred to, below, as *CLI tool* or *tool*) that allows you to connect to a Study Definitions Repository (SDR), get data about a study, and write data from that study into variables in an electronic Clinical Protocol Template (eCPT) document.

2. Prerequisites

You must meet the following prerequisites to install and use the tool.

- Windows 10 or Windows 11
- A way to run CLI applications, such as the cmd.exe, PowerShell, or Windows Terminal
- Credentials and API token that provide access to an instance of a Study Definition Repository (SDR) using the DDF SDR API

The Tool includes in its executable all its dependencies, including .NET 7 and third-party packages, so you do not have to install any dependencies before using the tool.

3. Installation

The SDRtoCPT tool does not have an installer. The steps below describe how to make the tool available on your computer.

1. Download/copy to your computer the zip file for the build (named DDF-[Version] where [Version] is the build number). **Important:** After you download the file, ensure it is unblocked.
    a. In Windows Explorer, find the zip file, right-click on it, and select **Properties**.
    b. Check the **Unblock** checkbox. **Note:** If **Unblock** is not visible, the file is already unblocked. Proceed to the next step.
    c. Select **OK**.
2. Extract the contents of the zip file.

You are now ready to use the tool.

3.1 Summary of Tool Artifacts

The package of artifacts for the tool is a zip archive with a name in the format **DDF-V.YY.MMDD.HHmm.zip** where:

- V = major version (0 for the PoC)
- YY = 2-digit year of the build
- MM = 2-digit month of the build
- DD = 2-digit day of the build
- HH = 2-digit hour of the build (on a 24-hour clock)
- mm = 2-digit minute of the build

Note: All date/time values are based on the date and time in universal coordinated time (UTC) when the build started.

The format described above is also the format for the version of the tool.

The package includes the following files.

- **Data** - folder for sample data
  - **CPT_v9_SDR_test.docx** - example eCPT document
  - **sdrtocpt_test_study_api_v3.json** - example JSON file with SDR data for a study
- **Documentation** - folder for documentation for the tool
  - **DDF CPT CLI Tool User Guide.docx** - documentation for how to use the tool
- **SDRtoCPT.exe** - executable file for the tool
- **settings.json** - JSON file with configuration settings for the tool

3.2 Summary of Tool Capabilities

At a high level, the tool can do the following:

- Display information about its build version and current configuration.
- Display its current configuration settings.
- Open, read, parse, and get values for configured fields from a JSON file that has SDR-formatted data for a study.
- Connect to and authenticate with a Study Definition Repository (SDR) via the SDR API, get JSON data for a study, parse it, and get values for configured fields.
- Open an eCPT Microsoft Word (.docx) file, read the list of CPT variables configured in the document, get the list of content controls in the document, and write values from SDR data to content controls for configured CPT variables.

Except for writing to an eCPT document, all other functions of the tool are read-only and do not create, update, nor delete data.

4. Tool Commands

The tool has the following commands.

- **about** - displays information about the tool.
- **config** - displays the current configuration.
- **study** - gets and displays study data and, optionally, writes the data to an eCPT document.

The **study** command has options that you use to specify tool behavior.

4.1 Run the Tool

To run the tool:

1. Open a shell, such as cmd.exe, PowerShell, or Windows Terminal in the folder that has **SDRtoCPT.exe**.
2. Type `SDRtoCPT.exe`, followed by the command and arguments that specify what you want the tool to do.
3. Press **Enter** to run the tool using the specified command and arguments.
4. When finished, you can close the shell by typing **Exit** and then pressing **Enter**.

When you run the tool with a command, the command must be the first thing after the executable, followed by any options you provide, as shown below.

The order of the options does not matter.

Tip: When you run the tool, you can omit the file extension (.exe) from the tool name. For brevity, the rest of the examples omit the file extension.

4.2 Get Tool Version

You can check the version of the tool by checking file properties or by running the tool.

To get the version from file properties:

1. Open Windows Explorer, right-click on **SDRtoCPT.exe**.
2. Select **Properties**.
3. Select **Details**.
4. View the value for **Product version**.

To get the version by running the tool:

1. Open a shell, such as cmd.exe, PowerShell, or Windows Terminal in the folder that has **SDRtoCPT.exe**.
2. Type the following and then press **Enter**.

```
SDRtoCPT.exe --version
```

The tool displays the version you are running, like below.

```
0.23.0724.1714-poc-uat
```

4.3 Get Tool Help

The tool has built-in documentation for the available commands and options.

To get information about the tool, type the following and then press **Enter**. To view that documentation, type the following and then press **Enter**.

```
SDRtoCPT --help
```

or

```
SDRtoCPT -h
```

When you use the help option (--help/-h) without a command, as shown above, the tool displays general help information, including a list of available commands. For example output from running the tool with only the **--help** option, see *7.1 Tool Help Example Output*.

Use the help option (--help or -h-) with a command to get more detailed help for that command. For example, to get help for the study command (*4.6 Study Command*), type the following and press **Enter**.

```
SDRtoCPT study --help
```

4.4 About command

The **about** command provides information about the build and configuration settings for the tool. To use the **about** command, type the following and then press **Enter**.

```
SDRtoCPT about
```

When you use the **about** command, the tool displays information about the build version, copyright, and the versions of the CPT, SDR API, and USDM that the current configuration supports. For example output from the **about** command see *7.2 About Command Example Output*.

4.5 Config command

The **config** command displays the current configuration in the *settings.json* file. To use the **config** command, type the following and then press **Enter**.

```
SDRtoCPT config
```

When you use the **config** command, the tool reads the *settings.json* file and displays the current settings and their values. For example output from the **config** command see *7.3 Config Command Example Output*.

4.6 Study Command

The **study** command reads SDR data, either from the SDR API or from a JSON file exported from an SDR, and, optionally, writes the data to content controls that represent variables in a CPT. When you use the **study** command, you supply options that tell the tool to get SDR data from either a JSON file or an SDR using the SDR API.

> **Note:** Getting SDR data, whether from a file or using the API, is read-only. The tool will not write or change any data unless you supply a CPT document (*4.6.3 Write Study Data to an eCPT Document*).

4.6.1 Get Study Data from a File

To get SDR data from a file, you must supply the following options to the **study** command.

- **--read-file** - path to a file that has JSON data in the same structure that the SDR API returns
- **--study-id** - GUID identifier within the SDR for the study record

> **Note:** You must supply a value for the **--study-id** option. The tool verifies that the file has data for the study with the ID you supply.

Below shows an example of using the **study** command to get data for a study with ID *71bfa56e-0cfd-4633-86bf-3c4474d3ea9c* from a file named *sdrtocpt_test_study_api_v3.json*.

```
SDRtoCPT study --read-file "sdrtocpt_test_study_api_v3.json" --study-id 71bfa56e-0cfd-4633-86bf-3c4474d3ea9c
```

For example output from the command above see *7.4 Study Command Example Study File Data* Output.

In the example above, the JSON file is in the same location as the tool. If the file is in another location, you must supply a full path or path that is relative to the location of the tool. The first example, below, shows supplying a relative path to a file that is in a directory below the directory that has the tool.

```
SDRtoCPT study --read-file "sub-directory\sdrtocpt_test_study_api_v3.json" --study-id 71bfa56e-0cfd-4633-86bf-3c4474d3ea9c --cpt-file "CPT_v9_SDR_test.docx"
```

The second example, below, shows supplying a full path to the file.

```
SDRtoCPT study --read-file "c:\my data folder\sdrtocpt_test_study_api_v3.json" --study-id 71bfa56e-0cfd-4633-86bf-3c4474d3ea9c --cpt-file "CPT_v9_SDR_test.docx"
```

Tip: Enclose file paths in quotation marks to ensure the tool reads them correctly when they have spaces in them.

4.6.2 Get Study Data from the SDR API

To get SDR data from an SDR, you use the **study** command with options that specify to use the SDR API. To get data from an SDR using the SDR API, you must omit the **--read-file** and supply the following options.

- **--api** - Boolean flag that is false by default and true when you include it with the **study** command.
- **--study-id** - GUID identifier in the SDR for the study record
- **--certificate** - path to the (.pfx) file with the certificate for your organization that is registered with the SDR instance that you are getting data from
- **--certificate-password** - password for the certificate
- **--token** - temporary API access token

Important: For information about the certificate and token, see the Study Definition Repository (SDR) Reference Implementation (RI) SDR API User Guide.

```
SDRtoCPT study --api --study-id 71bfa56e-0cfd-4633-86bf-3c4474d3ea9c --certificate "<certificate-file-name>.pfx" --certificate-password "<certificate-password>" --token "<token-from-sdr>"
```

For example output from the command above see *7.5 Study Command Example Study API Data Output*.

Tip: Use variables to store and supply values that you do not want to display on the command line, such as the certificate password and token. For information about setting a variable at the command line, see set (environment variable).

The code below shows an example of getting data from an SDR using the API by supplying values for the **--certificate-password** and **--token** options with variables named **certpwd** and **token**, respectively.

```
SDRtoCPT study --api --study-id 71bfa56e-0cfd-4633-86bf-3c4474d3ea9c --certificate "arborsys.pfx" --certificate-password %certpwd% --token %token%
```

Note: The tool builds the API URL from the configuration settings in the *settings.json* file. You can view those settings using the config command (*4.5 Config command*).

4.6.3 Write Study Data to an eCPT Document

To write data to a CPT document (Microsoft Word .docx file), you use the **study** command to get data, either from a file or SDR using the API, and supply the **--cpt-file** option with a path to the CPT document to which to write. Below shows an example of using the **study** command to get data for a study with ID `71bfa56e-0cfd-4633-86bf-3c4474d3ea9c` from a file named `sdrtocpt_test_study_api_v3.json` and writing the data to a CPT document named `CPT_v9_SDR_test.docx`.

```
SDRtoCPT study --read-file "sdrtocpt_test_study_api_v3.json" --study-id 71bfa56e-0cfd-4633-86bf-3c4474d3ea9c --cpt-file "CPT_v9_SDR_test.docx"
```

For an example of output from the above command, see *7.6 Study Command Example eCPT Writing Output* (p 12). For an example of the eCPT after running the above command, see *7.7 Study Command Example eCPT Document*.

5. Proof of Concept Scope and Limitations

The scope of the tool is a proof of concept to demonstrate automating getting SDR data, mapping it to CPT variables, and writing that data to content controls in an eCPT document. See *3.2 Summary of Tool Capabilities* for information about the in-scope functionality of the tool. As a proof of concept, the tool is not an end-to-end solution and has some limitations, including the following.

- The tool does not create content controls. If a content control for a mapped CPT variable does not exist in the content of the specified eCPT document, the tool has nowhere to which to write a value for the variable and the value does not get written to the document.
- The tool does not delete content controls. If more instances of content controls exist for a repeating variable (for example, objectives, endpoints, regulatory agency ID, or regulatory agency number) than there are values for the variable in the SDR data, the tool writes to only the number of content controls for which there are values and leaves the additional content controls. For example, if an eCPT document has four primary objective content controls and the SDR data has two primary objectives, then the tool writes the values to the first two primary objective content controls and does nothing with the two remaining content controls.
- Logging is not configurable and the tool writes log messages only to the console. You cannot change the logging level nor target of logging.

6. Troubleshoot

The list below describes common scenarios in which you may get unexpected results and how to troubleshoot them.

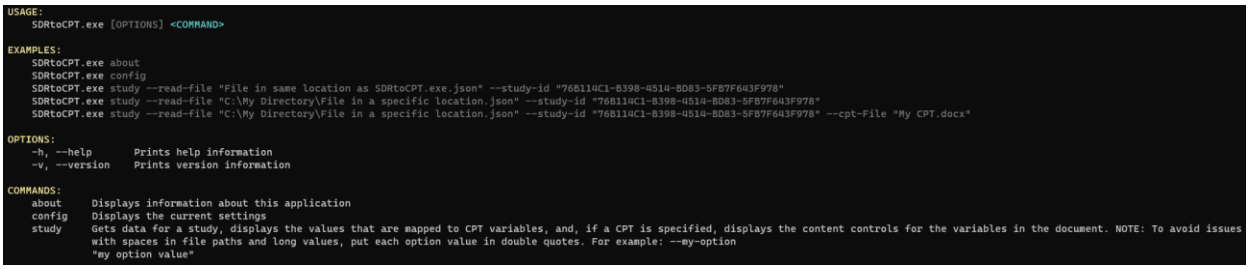
- `Unable to get study. Response status code: Unauthorized` - This usually indicates that you supplied an invalid or expired token. Getting a new token and supplying the new value with the **--token** option usually resolves this.
- `Error: Invalid file path. The specified path was: <path supplied>` - When getting data from a file, this indicates that the application could not find the file that you supplied with the **--read-file** option. Verify the path to the file and try again.
- `Could not find study ID study-id at JSON path $.studyDetails.studyId from <file-path>` - This indicates that the JSON file you supplied does not have the value you supplied for **--study-id** at the path that is set in the *settings.json* file. Verify the ID for the study you expect and/or supply a JSON file that has data for the study with the ID.
- `Error getting variables configured in <filename>` - This error is usually following in the log with an exception message that indicates that the eCPT file cannot be accessed because it is in use. Make sure that you do not have the document open and try again.

7. Appendix

This section shows example output from the commands and options shown in the documentation above.

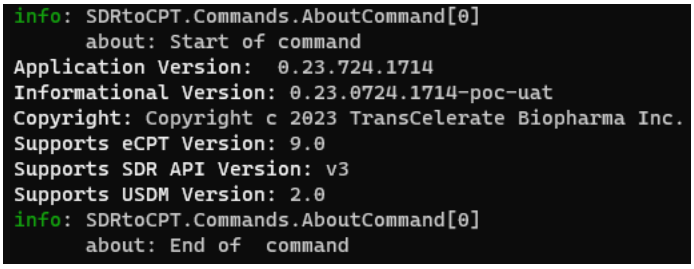
7.1 Tool Help Example Output

The example below shows output from running the tool with only the **--help** option (*4.3 Get Tool Help*).



7.2 About Command Example Output

The example below shows output from the **about** command (*4.4 About command*).



7.3 Config Command Example Output

The example below shows output from the **config** command (*4.5 Config command*).

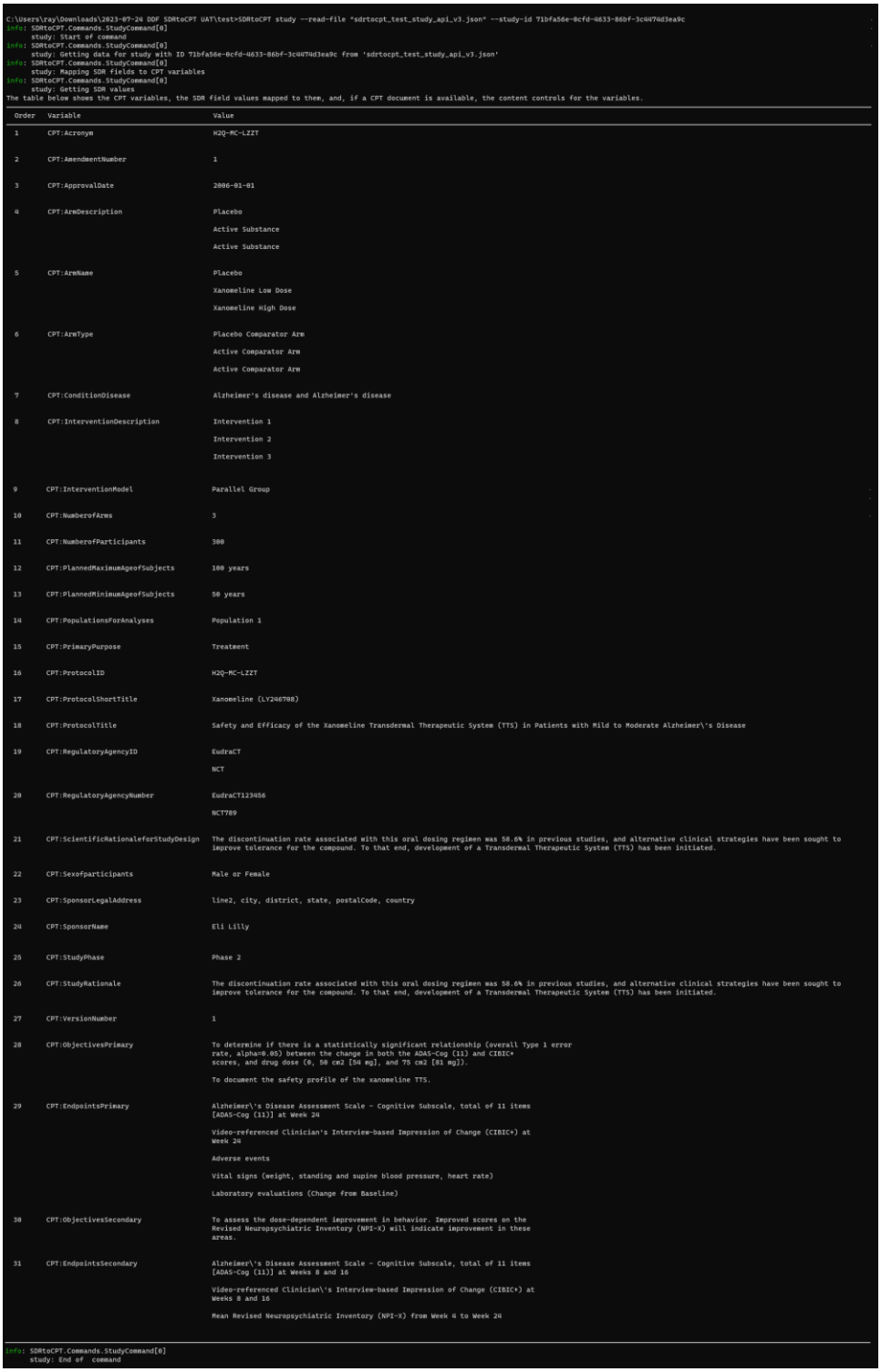
```
info: SDRtoCPT.Commands.ConfigCommand[0]
      config: Start of command
ApiEndpointGetStudy: v3/studydefinitions/{0}/studydesigns/ecpt
ApiServerUrl: https://apim-sdr-demo-eastus.azure-api.net/api/
ApiVersion: v3
CptVersion: 9.0
CdiscUsdmVersion: 2.0
Map: (31)
```

JsonPath	Functions	PathToChildren	Name	IsMultiple	Delimiter
$..ecptData.titlePage.acronym	None		CPT:Acronym	False	
$..ecptData.titlePage.amendmentNumber	None		CPT:AmendmentNumber	False	
$..ecptData.titlePage.approvalDate	None		CPT:ApprovalDate	False	
$..ecptData.studyInterventionsAndConcomitantTherapy.studyArms[*].armDescription	None		CPT:ArmDescription	True	
$..ecptData.studyInterventionsAndConcomitantTherapy.studyArms[*].armName	None		CPT:ArmName	True	
$..ecptData.studyInterventionsAndConcomitantTherapy.studyArms[*].armType	None		CPT:ArmType	True	
$..ecptData.titlePage.conditionDisease	None		CPT:ConditionDisease	False	
$..ecptData.studyInterventionsAndConcomitantTherapy.studyInterventionsAdministered[*].interventionDescription	None		CPT:InterventionDescription	True	
$..ecptData.protocolSummary.synopsis.interventionModel	None		CPT:InterventionModel	False	
$..ecptData.protocolSummary.synopsis.numberofArms	None		CPT:NumberofArms	False	
$..numberofParticipants	None		CPT:NumberofParticipants	False	
$..ecptData.studyPopulation.inclusionCriteria.plannedMaximumAgeofSubjects	Max		CPT:PlannedMaximumAgeofSubjects	False	
$..ecptData.studyPopulation.inclusionCriteria.plannedMinimumAgeofSubjects	Min		CPT:PlannedMinimumAgeofSubjects	False	
$..ecptData.statisticalConsiderations.populationsForAnalyses	None		CPT:PopulationsForAnalyses	False	,
$..ecptData.protocolSummary.synopsis.primaryPurpose	None		CPT:PrimaryPurpose	False	,
$..ecptData.titlePage.protocol.protocolID	None		CPT:ProtocolID	False	
$..ecptData.titlePage.protocol.protocolShortTitle	None		CPT:ProtocolShortTitle	False	
$..studyDetails.studyTitle	None		CPT:ProtocolTitle	False	
$..ecptData..regulatoryAgencyIdentifierNumbers[*].regulatoryAgencyId	None		CPT:RegulatoryAgencyID	True	
$..ecptData..regulatoryAgencyIdentifierNumbers[*].regulatoryAgencyNumber	None		CPT:RegulatoryAgencyNumber	True	
$..ecptData.introduction.studyRationale	None		CPT:ScientificRationaleforStudyDesign	False	
$..ecptData.studyPopulation.inclusionCriteria.sexofParticipants	Distinct		CPT:Sexofparticipants	False	/
$..ecptData.titlePage.sponsorLegalAddress	None		CPT:SponsorLegalAddress	False	
$..ecptData.titlePage.sponsorName	None		CPT:SponsorName	False	
$..ecptData.titlePage.studyPhase	None		CPT:StudyPhase	False	
$..ecptData.introduction.studyRationale	None		CPT:StudyRationale	False	
$..ecptData.pageHeader.versionNumber	None		CPT:VersionNumber	False	
$..ecptData.objectivesEndpointsAndEstimands.primaryObjectives[*].objectiveDescription	None	objectiveEndpoints[*].endpointDescription	CPT:ObjectivesPrimary	True	
$..ecptData.objectivesEndpointsAndEstimands.primaryObjectives[*].objectiveEndpoints[*].endpointDescription	None		CPT:EndpointsPrimary	True	
$..ecptData.objectivesEndpointsAndEstimands.secondaryObjectives[*].objectiveDescription	None	objectiveEndpoints[*].endpointDescription	CPT:ObjectivesSecondary	True	
$..ecptData.objectivesEndpointsAndEstimands.secondaryObjectives[*].objectiveEndpoints[*].endpointDescription	None		CPT:EndpointsSecondary	True	

```
info: SDRtoCPT.Commands.ConfigCommand[0]
      config: End of  command
```

7.4 Study Command Example Study File Data Output

The example below shows output from the **study** command getting study data from a file (*4.6.1 Get Study Data from a File*).



```
C:\Users\ray\Downloads\2023-07-24 DDF SDRtoCPT UAT\test>SDRtoCPT study --read-file "sdrtocpt_test_study_api_v3.json" --study-id 71bfa56e-0cfd-4633-86bf-3c4W74d3ea9c
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Start of command
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Getting data for study with ID 71bfa56e-0cfd-4633-86bf-3c4W74d3ea9c from 'sdrtocpt_test_study_api_v3.json'
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Mapping SDR fields to CPT variables
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Getting SDR values
The table below shows the CPT variables, the SDR field values mapped to them, and, if a CPT document is available, the content controls for the variables.
```

Order	Variable	Value
1	CPT:Acronym	H2Q-MC-LZZT
2	CPT:AmendmentNumber	1
3	CPT:ApprovalDate	2006-01-01
4	CPT:ArmDescription	Placebo Active Substance Active Substance
5	CPT:ArmName	Placebo Xanomeline Low Dose Xanomeline High Dose
6	CPT:ArmType	Placebo Comparator Arm Active Comparator Arm Active Comparator Arm
7	CPT:ConditionDisease	Alzheimer's disease and Alzheimer's disease
8	CPT:InterventionDescription	Intervention 1 Intervention 2 Intervention 3
9	CPT:InterventionModel	Parallel Group
10	CPT:NumberofArms	3
11	CPT:NumberofParticipants	300
12	CPT:PlannedMaximumAgeofSubjects	100 years
13	CPT:PlannedMinimumAgeofSubjects	50 years
14	CPT:PopulationsForAnalyses	Population 1
15	CPT:PrimaryPurpose	Treatment
16	CPT:ProtocolID	H2Q-MC-LZZT
17	CPT:ProtocolShortTitle	Xanomeline (LY246708)
18	CPT:ProtocolTitle	Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer\'s Disease
19	CPT:RegulatoryAgencyID	EudraCT NCT
20	CPT:RegulatoryAgencyNumber	EudraCT123456 NCT789
21	CPT:ScientificRationaleforStudyDesign	The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought to improve tolerance for the compound. To that end, development of a Transdermal Therapeutic System (TTS) has been initiated.
22	CPT:Sexofparticipants	Male or Female
23	CPT:SponsorLegalAddress	line2, city, district, state, postalCode, country
24	CPT:SponsorName	Eli Lilly
25	CPT:StudyPhase	Phase 2
26	CPT:StudyRationale	The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought to improve tolerance for the compound. To that end, development of a Transdermal Therapeutic System (TTS) has been initiated.
27	CPT:VersionNumber	1
28	CPT:ObjectivesPrimary	To determine if there is a statistically significant relationship (overall Type 1 error rate, alpha=0.05) between the change in both the ADAS-Cog (11) and CIBIC+ scores, and drug dose (0, 50 cm2 [54 mg], and 75 cm2 [81 mg]). To document the safety profile of the xanomeline TTS.
29	CPT:EndpointsPrimary	Alzheimer\'s Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] at Week 24 Video-referenced Clinician's Interview-based Impression of Change (CIBIC+) at Week 24 Adverse events Vital signs (weight, standing and supine blood pressure, heart rate) Laboratory evaluations (Change from Baseline)
30	CPT:ObjectivesSecondary	To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-X) will indicate improvement in these areas.
31	CPT:EndpointsSecondary	Alzheimer\'s Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] at Weeks 8 and 16 Video-referenced Clinician\'s Interview-based Impression of Change (CIBIC+) at Weeks 8 and 16 Mean Revised Neuropsychiatric Inventory (NPI-X) from Week 4 to Week 24

```
info: SDRtoCPT.Commands.StudyCommand[0]
      study: End of  command
```

7.5 Study Command Example Study API Data Output

The example below shows output from the **study** command getting study data from an SDR using the API (*4.6.2 Get Study Data from the SDR API*).

```
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Start of command
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Getting data for study with ID 71bfa56e-0cfd-4633-86bf-3c447d3ea9c from 'https://apim-sdr-demo-eastus.azure-api.net/api/v3/studydefinitions/71bfa56e-0cfd-4633-86bf-3c447d3ea9c/studydesigns/ecpt
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Mapping SDR fields to CPT variables
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Getting SDR values
The table below shows the CPT variables, the SDR field values mapped to them, and, if a CPT document is available, the content controls for the variables.
```

Order	Variable	Value
1	CPT:Acronym	H2Q-MC-LZZT
2	CPT:AmendmentNumber	1
3	CPT:ApprovalDate	2006-01-01
4	CPT:ArmDescription	Placebo Active Substance Active Substance
5	CPT:ArmName	Placebo Xanomeline Low Dose Xanomeline High Dose
6	CPT:ArmType	Placebo Comparator Arm Active Comparator Arm Active Comparator Arm
7	CPT:ConditionDisease	Alzheimer's disease and Alzheimer's disease
8	CPT:InterventionDescription	Intervention 1 Intervention 2 Intervention 3
9	CPT:InterventionModel	Parallel Group
10	CPT:NumberofArms	3
11	CPT:NumberofParticipants	300
12	CPT:PlannedMaximumAgeofSubjects	100 years
13	CPT:PlannedMinimumAgeofSubjects	50 years
14	CPT:PopulationsForAnalyses	Population 1
15	CPT:PrimaryPurpose	Treatment
16	CPT:ProtocolID	H2Q-MC-LZZT
17	CPT:ProtocolShortTitle	Xanomeline (LY246708)
18	CPT:ProtocolTitle	Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer\'s Disease
19	CPT:RegulatoryAgencyID	EudraCT NCT
20	CPT:RegulatoryAgencyNumber	EudraCT123456 NCT789
21	CPT:ScientificRationaleforStudyDesign	The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought to improve tolerance for the compound. To that end, development of a Transdermal Therapeutic System (TTS) has been initiated.
22	CPT:Sexofparticipants	Male or Female
23	CPT:SponsorLegalAddress	line2, city, district, state, postalCode, country
24	CPT:SponsorName	Eli Lilly
25	CPT:StudyPhase	Phase 2
26	CPT:StudyRationale	The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought to improve tolerance for the compound. To that end, development of a Transdermal Therapeutic System (TTS) has been initiated.
27	CPT:VersionNumber	1
28	CPT:ObjectivesPrimary	To determine if there is a statistically significant relationship (overall Type 1 error rate, alpha=0.05) between the change in both the ADAS-Cog (11) and CIBIC+ scores, and drug dose (0, 50 cm2 [54 mg], and 75 cm2 [81 mg]). To document the safety profile of the xanomeline TTS.
29	CPT:EndpointsPrimary	Alzheimer\'s Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] at Week 24 Video-referenced Clinician's Interview-based Impression of Change (CIBIC+) at Week 24 Adverse events Vital signs (weight, standing and supine blood pressure, heart rate) Laboratory evaluations (Change from Baseline)
30	CPT:ObjectivesSecondary	To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-X) will indicate improvement in these areas.

7.6 Study Command Example eCPT Writing Output

The example below shows output from the **study** command getting study data from a file and writing data to an eCPT document.

```
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Start of command
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Getting data for study with ID 71bfa56e-0cfd-4633-86bf-3c4479d3ea9c from 'sdrtocpt_test_study_api_v3.json'
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Mapping SDR fields to CPT variables
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Getting SDR values
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Getting variables and content controls in 'CPT_v9_SDR_test.docx'
The table below shows the CPT variables, the SDR field values mapped to them, and the content controls for the variables.
```

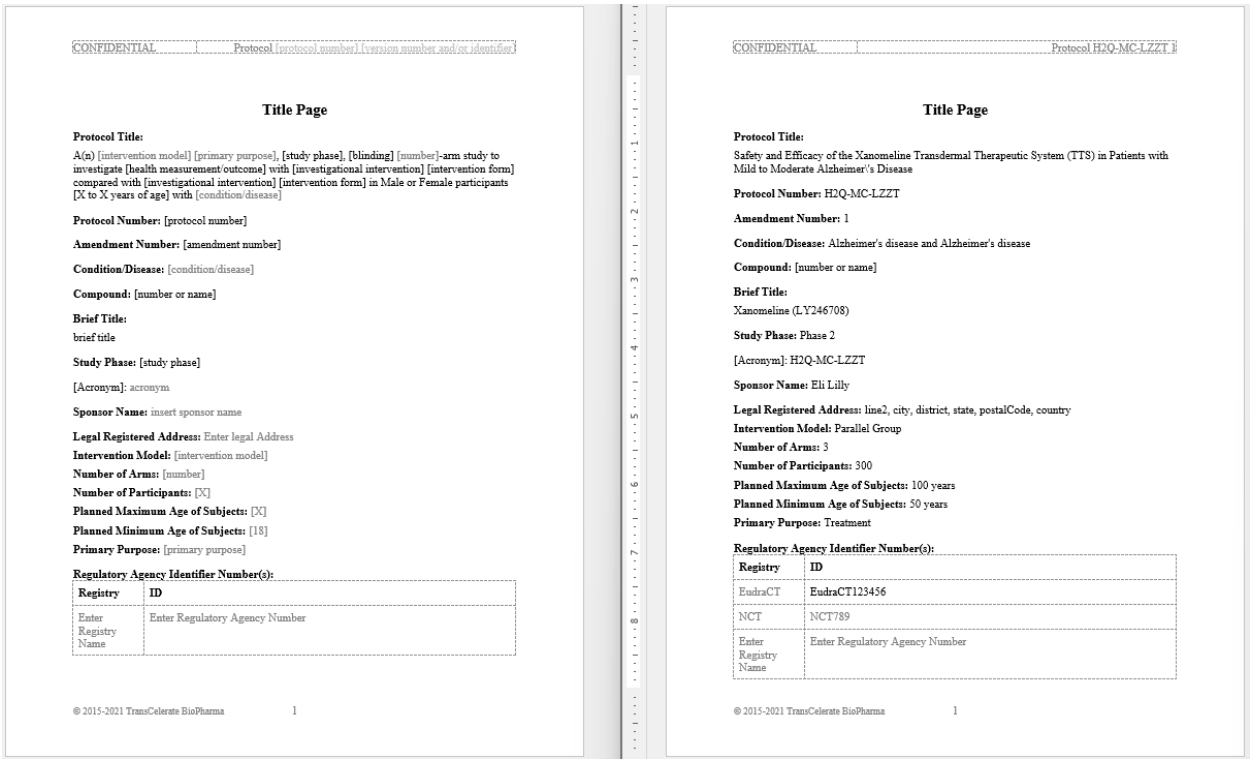
Order	Variable	Value	Content Controls
1	CPT:Acronym	H2Q-MC-LZZT	CPT:Acronym
2	CPT:AmendmentNumber	1	CPT:AmendmentNumber
3	CPT:ApprovalDate	2086-01-01	CPT:ApprovalDate
4	CPT:ArmDescription	Placebo	CPT:ArmDescription[1]
		Active Substance	CPT:ArmDescription[2]
		Active Substance	CPT:ArmDescription[3]
5	CPT:ArmName	Placebo	CPT:ArmName[1]
		Xanomeline Low Dose	CPT:ArmName[2]
		Xanomeline High Dose	CPT:ArmName[3]
6	CPT:ArmType	Placebo Comparator Arm	CPT:ArmType[1]
		Active Comparator Arm	CPT:ArmType[2]
		Active Comparator Arm	CPT:ArmType[3]
7	CPT:ConditionDisease	Alzheimer's disease and Alzheimer's disease	CPT:ConditionDisease
8	CPT:InterventionDescription	Intervention 1	CPT:InterventionDescription[1]
		Intervention 2	CPT:InterventionDescription[2]
		Intervention 3	CPT:InterventionDescription[3]
9	CPT:InterventionModel	Parallel Group	CPT:InterventionModel
10	CPT:NumberofArms	3	CPT:NumberofArms
11	CPT:NumberofParticipants	300	CPT:NumberofParticipants
12	CPT:PlannedMaximumAgeofSubjects	100 years	CPT:PlannedMaximumAgeofSubjects
13	CPT:PlannedMinimumAgeofSubjects	50 years	CPT:PlannedMinimumAgeofSubjects
14	CPT:PopulationsForAnalyses	Population 1	CPT:PopulationsForAnalyses
15	CPT:PrimaryPurpose	Treatment	CPT:PrimaryPurpose
16	CPT:ProtocolID	H2Q-MC-LZZT	CPT:ProtocolID
17	CPT:ProtocolShortTitle	Xanomeline (LY246708)	CPT:ProtocolShortTitle
18	CPT:ProtocolTitle	Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer\'s Disease	CPT:ProtocolTitle
19	CPT:RegulatoryAgencyID	EudraCT	CPT:RegulatoryAgencyID[1]
		NCT	CPT:RegulatoryAgencyID[2]
20	CPT:RegulatoryAgencyNumber	EudraCT123456	CPT:RegulatoryAgencyNumber[1]
		NCT789	CPT:RegulatoryAgencyNumber[2]
21	CPT:ScientificRationaleforStudyDesign	The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought to improve tolerance for the compound. To that end, development of a Transdermal Therapeutic System (TTS) has been initiated.	CPT:ScientificRationaleforStudyDesign
22	CPT:Sexofparticipants	Male or Female	CPT:Sexofparticipants
23	CPT:SponsorLegalAddress	line2, city, district, state, postalCode, country	CPT:SponsorLegalAddress
24	CPT:SponsorName	Eli Lilly	CPT:SponsorName
25	CPT:StudyPhase	Phase 2	CPT:StudyPhase
26	CPT:StudyRationale	The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought to improve tolerance for the compound. To that end, development of a Transdermal Therapeutic System (TTS) has been initiated.	CPT:StudyRationale
27	CPT:VersionNumber	1	CPT:VersionNumber
28	CPT:ObjectivesPrimary	To determine if there is a statistically significant relationship (overall Type 1 error rate, alpha=0.05) between the change in both the ADAS-Cog (11) and CIBIC+ scores, and drug dose (0, 50 cm2 [54 mg], and 75 cm2 [81 mg]).	CPT:ObjectivesPrimary[1]\r CPT:ObjectivesPrimary[2]\r
		To document the safety profile of the xanomeline TTS.	
29	CPT:EndpointsPrimary	Alzheimer\'s Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] at Week 24	CPT:EndpointsPrimary[1:1]\r
			CPT:EndpointsPrimary[1:2]\r
		Video-referenced Clinician's Interview-based Impression of Change (CIBIC+) at Week 24	CPT:EndpointsPrimary[2:1]\r
		Adverse events	CPT:EndpointsPrimary[2:2]\r
		Vital signs (weight, standing and supine blood pressure, heart rate)	CPT:EndpointsPrimary[2:3]\r
		Laboratory evaluations (Change from Baseline)	
30	CPT:ObjectivesSecondary	To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-X) will indicate improvement in these areas.	CPT:ObjectivesSecondary[1]
31	CPT:EndpointsSecondary	Alzheimer\'s Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] at Weeks 8 and 16	CPT:EndpointsSecondary[1:1]
			CPT:EndpointsSecondary[1:2]
		Video-referenced Clinician\'s Interview-based Impression of Change (CIBIC+) at Weeks 8 and 16	CPT:EndpointsSecondary[1:3]
		Mean Revised Neuropsychiatric Inventory (NPI-X) from Week 4 to Week 24	

```
info: SDRtoCPT.Commands.StudyCommand[0]
      study: Writing to 'CPT_v9_SDR_test.docx'
info: SDRtoCPT.Commands.StudyCommand[0]
```

7.7 Study Command Example eCPT Document

The examples below show an eCPT document before and after using the **study** command to write to it (*4.6.3 Write Study Data to an eCPT Document*). In each example, the left side shows the document content before running the tool and the right side shows the document after writing to it using the tool.

The example below shows the start of the title page content.



CONFIDENTIAL | Protocol [protocol number] [version number and/or identifier]

Title Page

Protocol Title:

A(n) [intervention model] [primary purpose], [study phase], [blinding] [number]-arm study to investigate [health measurement/outcome] with [investigational intervention] [intervention form] compared with [investigational intervention] [intervention form] in Male or Female participants [X to X years of age] with [condition/disease]

Protocol Number: [protocol number]

Amendment Number: [amendment number]

Condition/Disease: [condition/disease]

Compound: [number or name]

Brief Title:

brief title

Study Phase: [study phase]

[Acronym]: acronym

Sponsor Name: insert sponsor name

Legal Registered Address: Enter legal Address

Intervention Model: [intervention model]

Number of Arms: [number]

Number of Participants: [X]

Planned Maximum Age of Subjects: [X]

Planned Minimum Age of Subjects: [18]

Primary Purpose: [primary purpose]

Regulatory Agency Identifier Number(s):

Registry	ID
Enter Registry Name	Enter Regulatory Agency Number

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CONFIDENTIAL | Protocol H2Q-MC-LZZT

Title Page

Protocol Title:

Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer\'s Disease

Protocol Number: H2Q-MC-LZZT

Amendment Number: 1

Condition/Disease: Alzheimer's disease and Alzheimer's disease

Compound: [number or name]

Brief Title:

Xanomeline (LY246708)

Study Phase: Phase 2

[Acronym]: H2Q-MC-LZZT

Sponsor Name: Eli Lilly

Legal Registered Address: line2, city, district, state, postalCode, country

Intervention Model: Parallel Group

Number of Arms: 3

Number of Participants: 300

Planned Maximum Age of Subjects: 100 years

Planned Minimum Age of Subjects: 50 years

Primary Purpose: Treatment

Regulatory Agency Identifier Number(s):

Registry	ID
EudraCT	EudraCT123456
NCT	NCT789
Enter Registry Name	Enter Regulatory Agency Number

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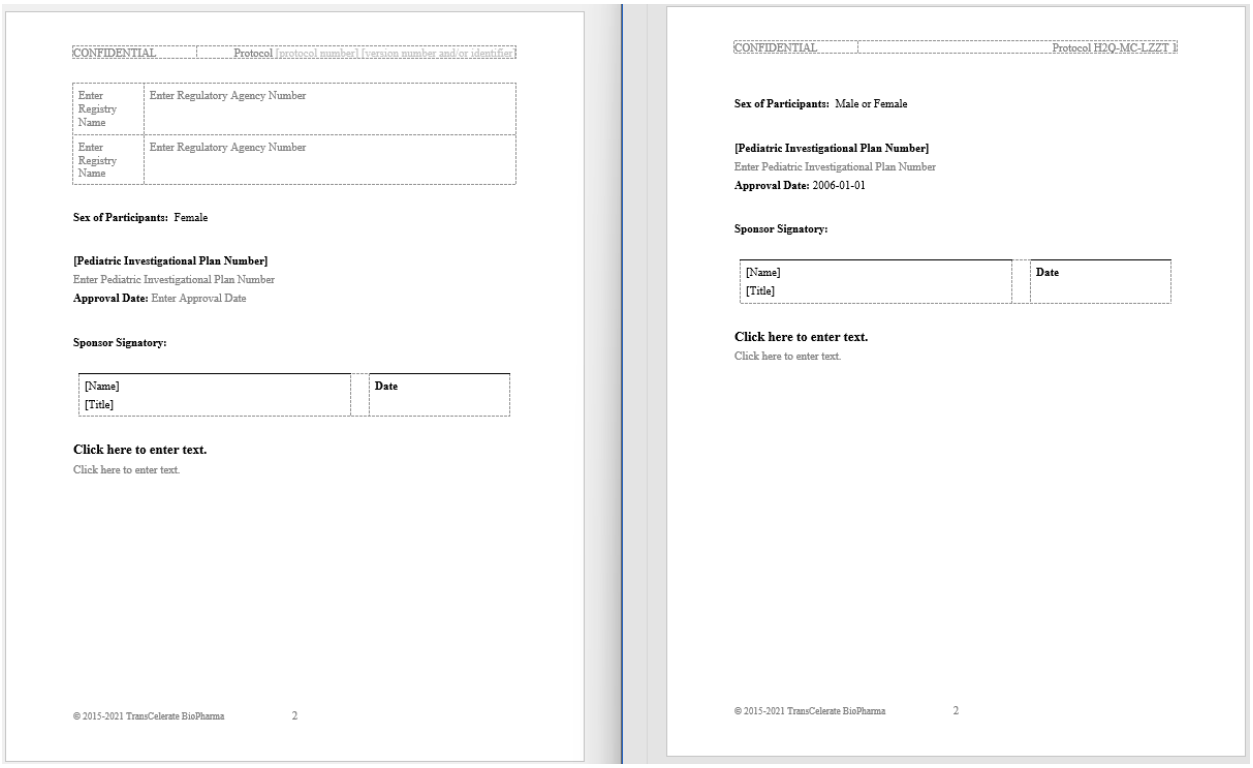
The example below shows the next page of the title page content.



CONFIDENTIAL | Protocol [protocol number] [version number and/or identifier]

Enter Registry Name	Enter Regulatory Agency Number
Enter Registry Name	Enter Regulatory Agency Number

Sex of Participants: Female

[Pediatric Investigational Plan Number]
Enter Pediatric Investigational Plan Number
Approval Date: Enter Approval Date

Sponsor Signatory:

[Name] [Title]	**Date**

Click here to enter text.
Click here to enter text.

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CONFIDENTIAL | Protocol H2Q-MC-LZZT [

Sex of Participants: Male or Female

[Pediatric Investigational Plan Number]
Enter Pediatric Investigational Plan Number
Approval Date: 2006-01-01

Sponsor Signatory:

[Name] [Title]	**Date**

Click here to enter text.
Click here to enter text.

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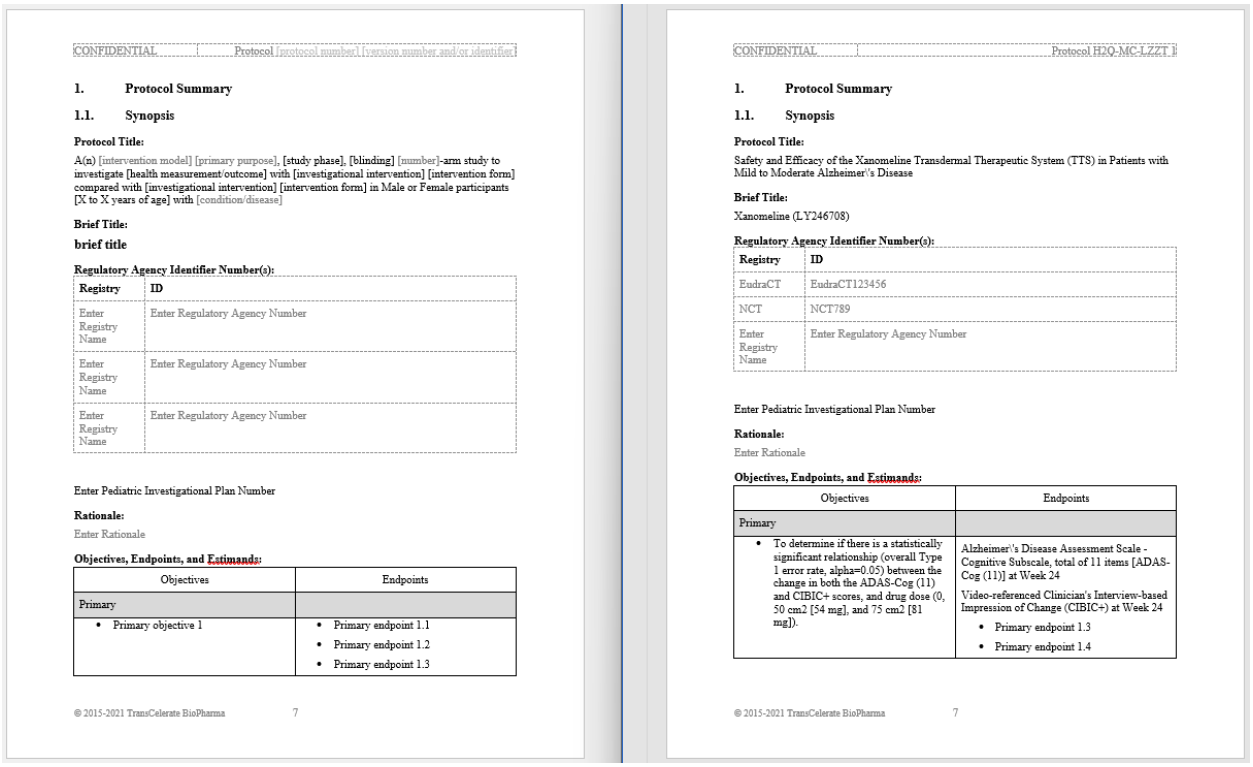
The example below shows the start of the *Protocol Summary* section.



CONFIDENTIAL | Protocol [protocol number] [version number and/or identifier]

1. Protocol Summary

1.1. Synopsis

Protocol Title:
A(n) [intervention model] [primary purpose], [study phase], [blinding] [number]-arm study to investigate [health measurement/outcome] with [investigational intervention] [intervention form] compared with [investigational intervention] [intervention form] in Male or Female participants [X to X years of age] with [condition/disease]

Brief Title:
brief title

Regulatory Agency Identifier Number(s):

Registry	ID
Enter Registry Name	Enter Regulatory Agency Number
Enter Registry Name	Enter Regulatory Agency Number
Enter Registry Name	Enter Regulatory Agency Number

Enter Pediatric Investigational Plan Number

Rationale:
Enter Rationale

Objectives, Endpoints, and Estimands:

Objectives	Endpoints
Primary	
• Primary objective 1	• Primary endpoint 1.1 • Primary endpoint 1.2 • Primary endpoint 1.3

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CONFIDENTIAL | Protocol H2Q-MC-LZZT [

1. Protocol Summary

1.1. Synopsis

Protocol Title:
Safety and Efficacy of the Xanomeline Transdermal Therapeutic System (TTS) in Patients with Mild to Moderate Alzheimer's Disease

Brief Title:
Xanomeline (LY246708)

Regulatory Agency Identifier Number(s):

Registry	ID
EudraCT	EudraCT123456
NCT	NCT789
Enter Registry Name	Enter Regulatory Agency Number

Enter Pediatric Investigational Plan Number

Rationale:
Enter Rationale

Objectives, Endpoints, and Estimands:

Objectives	Endpoints
Primary	
• To determine if there is a statistically significant relationship (overall Type 1 error rate, alpha=0.05) between the change in both the ADAS-Cog (11) and CIBIC+ scores, and drug dose (0, 50 cm2 [54 mg], and 75 cm2 [81 mg]).	Alzheimer's Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] at Week 24 Video-referenced Clinician's Interview-based Impression of Change (CIBIC+) at Week 24 • Primary endpoint 1.3 • Primary endpoint 1.4

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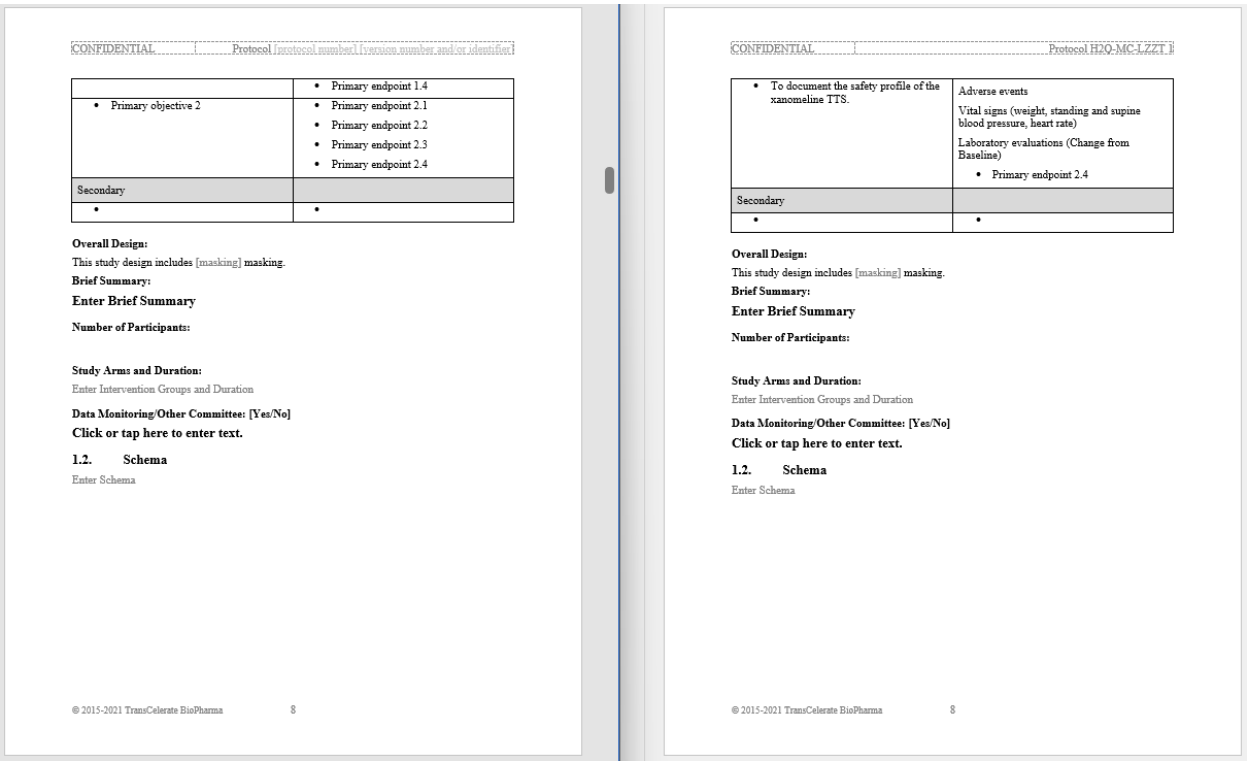
The example below shows the second page of the *Protocol Summary* section.



CONFIDENTIAL | Protocol [protocol number] [version number and/or identifier]

• Primary objective 2	• Primary endpoint 1.4 • Primary endpoint 2.1 • Primary endpoint 2.2 • Primary endpoint 2.3 • Primary endpoint 2.4
Secondary	
•	•

Overall Design:

This study design includes [masking] masking.

Brief Summary:

Enter Brief Summary

Number of Participants:

Study Arms and Duration:

Enter Intervention Groups and Duration

Data Monitoring/Other Committee: [Yes/No]

Click or tap here to enter text.

1.2. Schema

Enter Schema

CONFIDENTIAL | Protocol H2Q-MC-LZZT |

• To document the safety profile of the xanomeline TTS.	Adverse events Vital signs (weight, standing and supine blood pressure, heart rate) Laboratory evaluations (Change from Baseline) • Primary endpoint 2.4
Secondary	
•	•

Overall Design:

This study design includes [masking] masking.

Brief Summary:

Enter Brief Summary

Number of Participants:

Study Arms and Duration:

Enter Intervention Groups and Duration

Data Monitoring/Other Committee: [Yes/No]

Click or tap here to enter text.

1.2. Schema

Enter Schema

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The example below shows section *2.1 Study Rationale*.

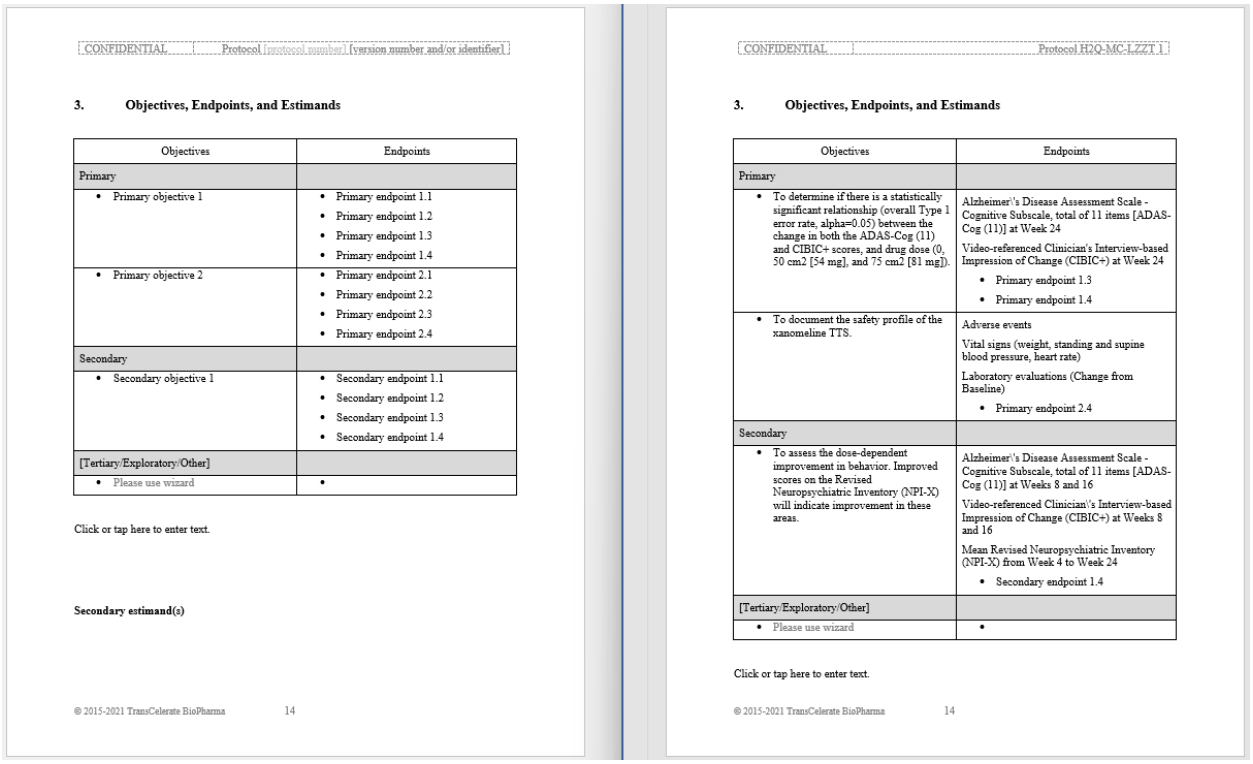
2.1. Study Rationale

Enter Rationale

2.1. Study Rationale

The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought to improve tolerance for the compound. To that end, development of a Transdermal Therapeutic System (TTS) has been initiated.

The example below shows section *3. Objectives, Endpoints, and Estimands*.



CONFIDENTIAL Protocol [protocol number] [version number and/or identifier]

3. Objectives, Endpoints, and Estimands

Objectives	Endpoints
Primary	
• Primary objective 1	• Primary endpoint 1.1 • Primary endpoint 1.2 • Primary endpoint 1.3 • Primary endpoint 1.4
• Primary objective 2	• Primary endpoint 2.1 • Primary endpoint 2.2 • Primary endpoint 2.3 • Primary endpoint 2.4
Secondary	
• Secondary objective 1	• Secondary endpoint 1.1 • Secondary endpoint 1.2 • Secondary endpoint 1.3 • Secondary endpoint 1.4
[Tertiary/Exploratory/Other]	
• Please use wizard	•

Click or tap here to enter text.

Secondary estimand(s)

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CONFIDENTIAL Protocol H2Q-MC-LZZT 1

3. Objectives, Endpoints, and Estimands

Objectives	Endpoints
Primary	
• To determine if there is a statistically significant relationship (overall Type 1 error rate, alpha=0.05) between the change in both the ADAS-Cog (11) and CIBIC+ scores, and drug dose (0, 50 cm2 [54 mg], and 75 cm2 [81 mg]).	Alzheimer\'s Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] at Week 24 Video-referenced Clinician's Interview-based Impression of Change (CIBIC+) at Week 24 • Primary endpoint 1.3 • Primary endpoint 1.4
• To document the safety profile of the xanomeline TTS.	Adverse events Vital signs (weight, standing and supine blood pressure, heart rate) Laboratory evaluations (Change from Baseline) • Primary endpoint 2.4
Secondary	
• To assess the dose-dependent improvement in behavior. Improved scores on the Revised Neuropsychiatric Inventory (NPI-X) will indicate improvement in these areas.	Alzheimer\'s Disease Assessment Scale - Cognitive Subscale, total of 11 items [ADAS-Cog (11)] at Weeks 8 and 16 Video-referenced Clinician\'s Interview-based Impression of Change (CIBIC+) at Weeks 8 and 16 Mean Revised Neuropsychiatric Inventory (NPI-X) from Week 4 to Week 24 • Secondary endpoint 1.4
[Tertiary/Exploratory/Other]	
• Please use wizard	•

Click or tap here to enter text.

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The example below shows section *4.2 Scientific Rationale for Study Design*.

4.2. Scientific Rationale for Study Design

4.2. Scientific Rationale for Study Design

The discontinuation rate associated with this oral dosing regimen was 58.6% in previous studies, and alternative clinical strategies have been sought to improve tolerance for the compound. To that end, development of a Transdermal Therapeutic System (TTS) has been initiated.

The example below shows the affected content in *Table 1. Study Intervention(s) Administered* in section *6.1 Study Interventions Administered*.

Intervention Description	[eg, dosage form, dosage, frequency]	[eg, dosage form, dosage, frequency]	[eg, dosage form, dosage, frequency]	[eg, dosage form, dosage, frequency]

Intervention Description	Intervention 1	Intervention 2	Intervention 3	[eg, dosage form, dosage, frequency]

The example below shows the affected content in *Table 2. Study Arm(s)* in section *6.1 Study Interventions Administered*.

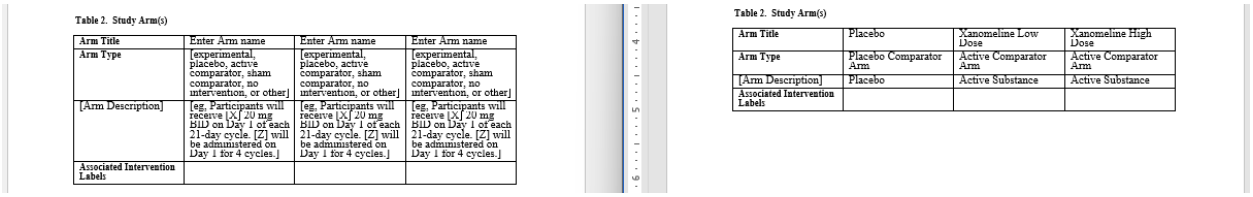

Table 2. Study Arm(s)

Arm Title	Enter Arm name	Enter Arm name	Enter Arm name
Arm Type	[experimental, placebo, active comparator, sham comparator, no intervention, or other]	[experimental, placebo, active comparator, sham comparator, no intervention, or other]	[experimental, placebo, active comparator, sham comparator, no intervention, or other]
[Arm Description]	[eg, Participants will receive [X] 20 mg BID on Day 1 of each 21-day cycle. [Z] will be administered on Day 1 for 4 cycles.]	[eg, Participants will receive [X] 20 mg BID on Day 1 of each 21-day cycle. [Z] will be administered on Day 1 for 4 cycles.]	[eg, Participants will receive [X] 20 mg BID on Day 1 of each 21-day cycle. [Z] will be administered on Day 1 for 4 cycles.]
Associated Intervention Labels			

Table 2. Study Arm(s)

Arm Title	Placebo	Xanomeline Low Dose	Xanomeline High Dose
Arm Type	Placebo Comparator Arm	Active Comparator Arm	Active Comparator Arm
[Arm Description]	Placebo	Active Substance	Active Substance
Associated Intervention Labels			