

Roche

The diagram illustrates the GDSR architecture. At the bottom, a large blue cylinder represents the **GDSR Infrastructure**. Inside this cylinder, there are two columns of orange boxes, each containing a molecular structure icon. The left column lists: **Domains**, **Research Concepts**, **Forms**, and **Study Design**. The right column lists: **Data Collection Modules**, **Data Elements**, **Fields**, and **Controlled Terminology**. Below these columns are three vertical dots. To the left of the cylinder, a vertical blue bar is labeled **Global Data Standards Repository (GDSR)**. Two orange boxes, **Study 1** and **Study 2**, are positioned to the left of the cylinder. Arrows labeled **References** point from these study boxes to the **Domains** and **Research Concepts** boxes in the left column. To the right of the cylinder, two orange boxes, **Study n** and an ellipsis (**...**), are positioned. Arrows labeled **References** point from the **Data Collection Modules** and **Data Elements** boxes in the right column to these study boxes. Above the GDSR Infrastructure is a red box labeled **Study Builder**. Inside this box, there are four yellow boxes arranged in a staircase pattern: **Study 1**, **Study 2**, an ellipsis (**...**), and **Study n**. A blue arrow labeled **Read Only** points from the GDSR Infrastructure up to the Study Builder. Two blue arrows, one on the left and one on the right, point from the Study Builder to the GDSR Infrastructure. The left arrow is labeled **Save to GDSR** and the right arrow is also labeled **Save to GDSR**.

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graph TD
    Study[Study] -- has summary --> Summary[Summary]
    Summary -- summary of --> PV[Protocol Version]
    PV -- version of --> Protocol[Protocol]
    PV -- has schedule --> Schedule[Schedule]
    Schedule -- has planned path --> Arm[Arm]
    Schedule -- has planned epoch --> Epoch[Epoch]
    Schedule -- has cell --> Cell[Cell]
    Cell -- has study activity --> SA[Study Activity]
    SA -- sub-activity of --> SA
    SA -- has planned activity --> PA[Planned Activity]
    PA -- has study event --> SE[Study Event]
    SE -- sub-event of --> SE
    SE -- has event reference --> SER[Study Event Reference]
    SE -- has event type --> SET[Study Event Type]
    SET -- has parent event type --> SET
    DE[Data Element] -- context --> Domain[Domain]
    Domain -- context --> DMC[Domain Module Context]
    DMC -- context --> DMC
    DMC -- context --> Model[Model]
    DCF[Data Collection Field] -- context --> DE
    DCF -- context --> DCM[Domain Component Module]
    DCM -- context --> DCM
    DCM -- context --> DMC
  
```

Study Design Overview							
	SCREENING	TREATMENT 1	BLINDED TREATMENT	OPEN LABEL TREATMENT	FOLLOW-UP 1	LONG-TERM FOLLOW-UP	Unscheduled
Placebo	Completed ¹	Not Started	Not Started	Empty	Completed ²	Completed ³	Not Started
Treatment A	Completed ¹	In Progress	Not Started	Not Started ⁴	Completed ²	Completed ³	Not Started
Treatment B	Completed ¹	Not Started	Not Started	Not Started ⁴	Completed ²	Completed ³	Not Started

Cell.Treatment A.TREATMENT 1

[CREATE NEW ACTIVITY](#)
[ADD STUDY EVENT](#)

Activity as given in Protocol	Cycle 1			Cycle 2			Cycle 3			Cycle 4			Cycle 5			
	Day 1	Day 8	Day 15	Day 1	Day 8	Day 15	Day 1	Day 8	Day 15	Day 1	Day 8	Day 15	Day 1	Day 8	Day 15	
Visit date	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Demographic data	X															
General medical history and baseline conditions	X															
Vital signs	TP			TP			TP			TP			TP			
Complete physical examination	X			X			X			X			X			
Chemistry/local lab	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Echocardiogram	X			X			X			X			X			
Treatment A	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Therapeutic Area

ACROSS TA

Status

☒ Standard
 ☒ Candidate
 ☐ Proposed

CRF/Non-CRF

☒ CRF
 ☒ Non-CRF

Search Activities

Demographic data

TP – Timepoints: Where data is collected multiple times at a single study event (visit) the user can define the time points used in the study.

[illegible]

	C	D	I	J	K	N	P	Q	T		
1	FormID	FieldID	Ordinal	VariableID	DataFormat	DictionaryName	ControlType	IsDefault	PreText	HelpText	IsLog
	CHML1	NOTDN	1	NOTDN	1		CheckBox	0	Not done	Select Not done if no specimen was collected, no results were obtained or the lab sample was insufficient, and leave the rest of the form blank.	FALSE
173	CHML1	COLD	2	COLD	dd-MMM-yyyy		DateTime	0	Collection date	Enter the complete date in dd MMM yyyy format.	FALSE
174	CHML1	LRCHM1	3	LRCHM1	S3		RadioButton	0	Add another chemistry form to the current folder?	Select Yes if another Chemistry Local 1 form is needed in this folder. Examples of reasons to add another form include adding another timepoint, repeat data or if not at more tests.	FALSE
						YES_NO_V1					
175	CHML1	SODIUM	4	SODIUM	12,4						
176	CHML1	POTASS	5	POTASS	12,4						
177	CHML1	CL	6	CL	12,4						
178	CHML1	BICARB	7	BICARB	12,4						
180	CHML1	GLUC	8	GLUC	12,4						
181	CHML1	UREA	9	UREA	12,4						
182	CHML1	BUN	10	BUN	12,4						
183	CHML1	CREAT	11	CREAT	12,4						
184	CHML1	TPROT	12	TPROT	12,4						
185	CHML1	ALBUM	13	ALBUM	12,4						
186	CHML1	CA	14	CA	12,4						
187	CHML1	MAG	15	MAG	12,4						
188	CHML1	BLU	16	BLU	12,4						
189	CHML1	BLDR	17	BLDR	12,4						
190	CHML1	ALP	18	ALP	12,4						
191	CHML1	SGPT	19	SGPT	12,4						
192	CHML1	SGOT	20	SGOT	12,4						
193	CHML1	GOT	21	GOT	12,4						
194	CHML1	PGREP1	22	PGREP1	\$20						
195	CHML1	FRMSRC	23	FRMSRC	\$10						

- Protocol SoA
- Generation of specifications for non-EDC data
- Submission-ready SDTM annotated CRFs
- SDTM Code Generator
- Interfaces with other internal systems