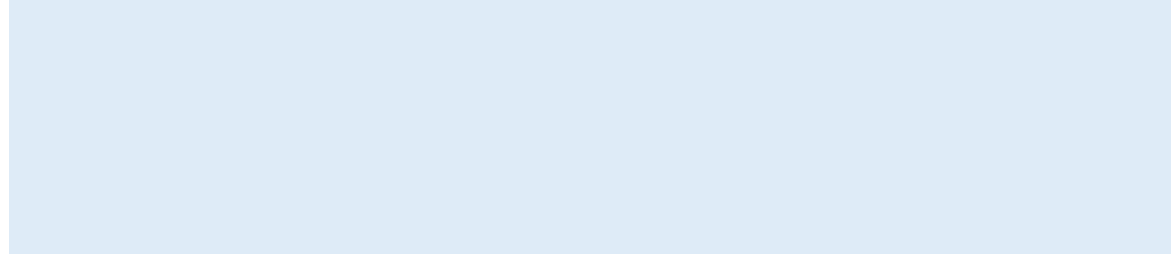
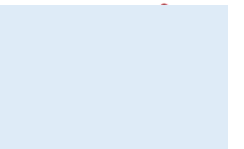


System Requirement Specification

Patient Support Program (PSP)



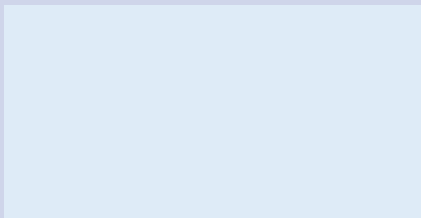
Developed By:



Required Heads

- Disease / Medicine Enlistment with Call Plan Schedule & Unique ID
- Patient Enrollment
- View All Patients
- Patient Profile
- Patient Counselling
- Adverse Event and SDV Reporting Status
- Dashboard

Disease / Medicine Enlistment with Call Plan Schedule & Unique ID

Disease Name	Medicine Name	Unique ID Generation	Call Schedule Planning
HF	- 	CHF XXXX	<ul style="list-style-type: none"> - Call Schedule for Patient - Call Schedule for Patient's Caregiver - "Add Topic" Option Against Each Call Plan - Specific Number of Day Setting Against Each Call Schedule
DME	Will Be Provided	DME XXXX	Will Be Provided
AMD	Will Be Provided	AMD XXXX	Will Be Provided
ASTHMO	Will Be Provided	AST XXXX	Will Be Provided
PSO	Will Be Provided	PSO XXXX	Will Be Provided
PSA	Will Be Provided	PSA XXXX	Will Be Provided
AxSpa	Will Be Provided	ASA XXXX	Will Be Provided

Remarks:

- There has to be an **"Add Disease"** option where the counsellor can add diseases (Disease Name) and add medicine name under the add disease option.
- The medicine name created under specific disease option should also come as dropdown after selection of disease name in the **"Patient Enrolment"** tab
- Unique ID will be created for each patient according to disease, approximately 5 digits after the first three letter.
Example: CHF 12345

Counselling Schedule Setting (Example)

Disease Name	Call Schedule	Counselling For	Counselling Topic
HF	Day 0 (Inbound)	Patient / Caregiver (Dropdown)	First Call Made by Patient
	Day 15 (15 th Day from Day 0)	Patient / Caregiver (Dropdown)	Topic 1 (Add Topic Option Needed)
	Day 30 (15 th Day from Day 15)	Patient / Caregiver (Dropdown)	Topic 2 (Add Topic Option Needed)
	Day 45 (15 th Day from Day 30)	Patient / Caregiver (Dropdown)	Topic 3 (Add Topic Option Needed)
	Day 60	Patient / Caregiver (Dropdown)	Topic 4
	Day 75	Patient / Caregiver (Dropdown)	Topic 5
	Day 90	Patient / Caregiver (Dropdown)	Topic 6
	Day 105	Patient / Caregiver (Dropdown)	Topic 7
	Day 120	Patient / Caregiver (Dropdown)	Topic 8
	Day 135	Patient / Caregiver (Dropdown)	Topic 9
	Day 150	Patient / Caregiver (Dropdown)	Topic 10
	Day 165	Patient / Caregiver (Dropdown)	Topic 11
	Day 180	Patient / Caregiver (Dropdown)	Topic 12
	Day 195	Patient / Caregiver (Dropdown)	Topic 13
	Day 210	Patient / Caregiver (Dropdown)	Topic 14
	Day 225	Patient / Caregiver (Dropdown)	Topic 15
	Day 240	Patient / Caregiver (Dropdown)	Topic 16
	Day 255	Patient / Caregiver (Dropdown)	Topic 17
	Day 270	Patient / Caregiver (Dropdown)	Topic 18
	Day 285	Patient / Caregiver (Dropdown)	Topic 19
	Day 300	Patient / Caregiver (Dropdown)	Topic 20
	Day 315	Patient / Caregiver (Dropdown)	Topic 21
	Day 330	Patient / Caregiver (Dropdown)	Topic 22
	Day 345	Patient / Caregiver (Dropdown)	Topic 23
	Day 360	Patient / Caregiver (Dropdown)	Topic 24

Patient Enrolment Information

Patient's Information

- Patient Name
- Gender
- Age
- Height
- Weight
- BMI (Auto Calculate)
- Location (District & Area)
- Profession
- District
- Area
- Registered Number
- Additional Number (If Any)
- Marital Status (Married / Unmarried)
- Occupation (Govt. Job / Private Job / Business / Retired)
- Treating Physician's Name
- Chamber Address
- Family Medical History (Comment Box)
- Patient's Health Data (Comment Box)
- Lifestyle Information (Smoking / Drinking / Other)
- Disability Information (Fully Disabled / Partially Disabled- Can Move / Partially Disabled- Can't Move / Fully Functional)
- Date of enrolment (Call schedule will be set taking it as base)
- Others (Comment Box)

Caregiver's Information

- Caregiver Name
- Gender
- Age
- Contact Number
- Relationship with Patient
- Others (Comment Box)

Enrolment Information Collected From

- Patient / Caregiver (Dropdown)

Unique ID Generation

- Unique ID will be generated and a SMS will be sent to the patient upon clicking the "Save" button in a pre-set format

Disease Selection

- Select disease from dropdown list

Medicine Selection

- Select medicine from dropdown, along with dose administration

Call Schedule

- Will be set automatically upon selection of disease

Enrolment Information Collection From

- Patient / Caregiver

All Patients

- Show a list of all patients enrolled in PSP Program
- Search Patients with Unique ID and Phone Number (Registered / Additional / Caregiver Number)
- Filter Patients- Disease Wise, Medicine Wise, Date Wise



Patient Name	Disease	Unique ID	Medicine	Enrolment Date	Status	Profile
Enamul Kabir 018182639XX	HCF	HCF 12345		June 10, 2022	Active	Click
Ishtiak Azim 017754800XX	DME	HCF 12346		June 05, 2022	Inactive	Click

Patient Profile

Following Things Will Be Included In Patient Profile:

- Patient Enrolment Information (Slide 5) with Edit Option [Edit Information Will Be Password Protected]
 - Personal
 - Medial Information
 - Treating Physician
 - Medicine Name
 - Caregiver Information
- Patient's Counselling History (Scheduled + Inbound) with Adverse Event Detection Status
 - Schedule Date (Editing the schedule date will not affect the next schedule date)
 - Counselling Topic
 - Status
 - Provided To
 - Adverse Event
 - Remarks

Enamul Kabir

Unique ID: HCF 12345

DOE: June 10, 2022

Personal

Name, Gender, Age, District, Area, Height, Weight, Profession, Registered Number, Additional Number, Marital Status, Occupation, Lifestyle Information, Disability Information

Medical Information

BMI, Family Medical History, Patient Health Data

Treating Physician

Physician Name, Designation & Chamber Address

Medicine Name

Novartis Medicine Name with Dose Administration

Caregiver Information

Caregiver Details

Counselling Schedule Status

<u>Schedule Date</u>		<u>Counselling Topic</u>	<u>Status</u>	<u>Provided To</u>	<u>Adverse Event</u>	<u>Counsellor</u>	<u>Remarks</u>
June 15	Edit	Topic 1	Provided	Patient	No	Dr. Rahat	
June 30	Edit	Topic 2	Provided	Caregiver	Yes	Dr. Maidul	
July 15	Edit	Topic 3	Pending				
July 30	Edit	Topic 4	Pending				
August 15	Edit	Topic 5	Pending				
August 30	Edit	Topic 6	Pending				
September 15	Edit	Topic 7	Pending				
September 30	Edit	Topic 8	Pending				
October 15	Edit	Topic 9	Pending				
October 30	Edit	Topic 10	Pending				

Patient Counselling

Following Things Will Be Included In Patient Counselling:

- Patient Listing for Counselling
 - Disease Wise
 - Date Wise
 - Topic Wise
- Counselling Status
 - Counselling Schedule
 - Inbound Query
- Start Counselling Panel Modality

Patient Listing for Counselling

From

To

Phone No

Disease▼

Topic▼

Unique ID

Search

Download

Patient Name	Disease	Unique ID	Next Counselling Topic	Date	Counselling Details
Enamul Kabir 018182639XX	HCF	HCF 12345	Topic 1	June 15, 2022	Click
Ishtiak Azim 01775480033	DME	HCF 12346	Topic 2	June 30, 2022	Click

Patient Wise Counselling Status

Counselling Schedule Status

Schedule Date	Counselling Topic	Status	Provided To	Adverse Event	Counsellor	Preferable Time	Remarks
June 15	Topic 1	Provided	Patient	No	Dr. Rahat	10:00 AM	
June 30	Topic 2	Provided	Caregiver	Yes	Dr. Maidul	5:30 PM	
July 15	Topic 3	Pending				12:30 PM	
July 30	Topic 4	Pending					

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Inbound Counselling Status

Schedule Date	Call Type	Provided To	Adverse Event	Counsellor	Remarks
June 1	Enrolment	Patient	No	Dr. Rahat	
June 25	Query	Caregiver	Yes	Dr. Maidul	
July 3	Query	Patient	No	Dr. Rahat	

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Start Counselling

Start Counselling

Patient Name: Enamul Kabir

Unique ID: HCF 12345

Counselling Type:

Scheduled Counselling (SC) / Enrollment / Query (Dropdown)

If SC

Topic Selection:

Select Topic (from Dropdown)

Counselling Provided To:

Patient / Caregiver (Dropdown)

Counselling Discussion (Remarks):

Box Field

Adverse Event Detection:

Yes / No (Dropdown)

Adverse Events:

- 1.
- 2.
- 3.

Will hit the adverse event (AE)
Section Along with ID

Will be marked as "Provided" in
case of SC on the "Status"
section of Patient Counselling
and Patient Profile

Reason, Date, Time & Remarks

Will hit in Patient Counselling
and Patient Profile

Reschedule

Save

Adverse Event Reporting and Source Data Verification

From

To

Phone No

Disease▼



Medicine▼

Unique ID

Search

Download

AE ID	Disease	Patient Name	Unique ID	Medicine	Detection Date	Time	SDV	SDV Status
AE10001	HCF	Enamul Kabir 018182639XX	HCF 12345		June 10	10:25 AM	Complete	Correct
AE10002	DME	Ishtiak Azim 017754800XX	HCF 12346		June 12	1:33 PM	Pending	Incorrect

AE Report Submitted By	SDV Performed By	AE Reporting Status	Submission Date & Time	Remarks
Dr. Rahat	Meherin Mostarina	Reported	June 10, 4:00 PM	
Dr. Maidul	Meherin Mostarina	Pending		

Dashboard

Following Things Will Be Included In The PSP Dashboard:

- Disease and Date Wise Number of **Patient Enrollment** (Cumulative and Disease Category Wise)
- Show Date Wise **Counselling Schedule** for the counsellors (Number and Patient List Along with Topic)
- Analytical View of Disease Wise **Patient Enrollment**
- Date Wise **Number of Counselling Provided**
- Number of **Inbound and Outbound Calls (Scheduled Calls)** Made (Disease Wise)
- Date Wise Number of **Rescheduled Calls**
- Counselling Time Schedule **Notification**
- Gender and Disease Wise **Patient Information**
- Date Wise **AE** Feedback **Received and Reported** to Novartis
- Date Wise Number of **SDV Performed** (Graph)

Thank You

Changes in SRS

- Unique ID will be 4 digits after Alphabetic Format. Example: CHF 1234 (Slide 3)
- File in the remarks option should contain the things mentioned in Slide 12
- Role creation option for counsellors and SDV
- AE Reporting Status: Reported (When Email is sent from system), Submitted (When email is sent manually, counsellor will change the remarks), Pending (Slide 13)
- Topic Creation for Specific Diseases (Slide 4)
- Topic Assign Option to Counsellors
- AE Reporting Format will be Different than Counselling Format