

**Study Master Base - UX User Story Mapping**

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**SAP Fiori Launchpad Home Page (Central Entry Point)**

**EPIC CTSM-432**  
Access and Navigation  
**CTS-M-436**  
As a Trial Manager, I want to have a central entry point and access to all my relevant applications, so that I can work on my clinical supply chain tasks.

**EPIC CTSM-9**  
Create Study Master for Protocol(s)  
**CTS-M-253**  
As a Trial Manager, I want to have an overview of all my existing studies including their status so that I can easily identify the ones which need further input from me.  
**CTS-M-457**  
As a Trial Manager, I want to have access to the study creation wizard so that I can create a study on my entry page directly.

**Clinical Trial Supply Management**

- Clinical Trial Supplies Cockpit**: Shows Active (1), Ongoing (7) studies. Buttons: Create New Study, Recently Used Studies (4), My Favorite Studies (3), Study Templates (4).
- Study Archive**: Shows Studies completed (5), Affected studies (0), Projects (8), Studies included (3), Studies changed (4).
- Approval Requests**: Shows Request Type 1 (2), Request Type 2 (1), Request Type 3 (1).
- Stock Level**: Shows Available quantities in 2019 for items like AG7700 100mg (9%), AB6341 200mg (45%), AD6421 300mg (22%), AB4263 100mg (85%).
- Shell Life Modifications**: Shows 3 modifications.
- My Compounds**: Shows 32 compounds.

**CTMS** Clinical Trial Management System   **DMS** Document Management System   **IRT** Interactive Response Technology   **EudraCT** Clinical Trials Register   **IRON** Integrated Regulatory Operations Network

**EPIC CTSM-9**  
Create Study Master for Protocol(s)  
**CTS-M-55**  
As a Trial Manager, I want to see my recently used study objects, so that I have the opportunity to resume my work.  
**CTS-M-456**  
As a Trial Manager, I want to be able to mark study objects as favorite, so that I can directly access them from my entry point.

**EPIC CTSM-454**  
As a System Owner I want to have the opportunity to include other applications to my entry point so that the end user can have one single entry point.

**List Report (Overview of Studies)**

**CTS-M-253**  
As a Trial Manager, I want to have an overview of all my existing studies including their status so that I can easily identify the ones which need further input from me.

**CTS-M-459**  
As a Trial Manager, I want to create a basic study master object with some header data, so that I can see the created object in my system and continue to work on it afterwards.

**CTS-M-456**  
As a Trial Manager, I want to be able to mark study objects as favorite, so that I can directly access them from my entry point.

**Clinical Studies (9)**

Study ID	Study Description	Project	Study Status	Study Type	Study Phase	Inventory Status	PPFV	LPPV	LPLV
20000109	SAP TMC E2E 09	BI 811283	New	Double-blind randomized	III		Oct 20, 2019	Apr 20, 2020	Apr 20, 2021
20000108	SAP TMC E2E 08	A08XAX01	Active	Double-blind randomized	IIa & IIb	80%	Sep 18, 2019	Mar 18, 2020	Mar 18, 2021
20000107	SAP TMC E2E 07	BI 811900	Ongoing	Dose escalation	IIa & IIb	98%	Aug 15, 2019	Feb 15, 2020	Feb 15, 2021
20000106	SAP TMC E2E 06	A08XFT03	Ongoing	Titration	IIb	100%	Jul 14, 2019	Jan 14, 2020	Jan 14, 2021
20000105	SAP TMC E2E 05	BI 811835	Ongoing	Double-blind randomized	II	74%	Jun 13, 2019	Dec 13, 2019	Dec 13, 2020
20000104	SAP TMC E2E 04	A08XAZ90	Ongoing	Titration	IIa & IIb	76%	May 10, 2019	Nov 10, 2019	Nov 10, 2020
20000103	SAP TMC E2E 03	BI 819903	Ongoing	Dose escalation	IIa	100%	Apr 8, 2019	Oct 8, 2019	Oct 8, 2020
20000102	SAP TMC E2E 02	A08XAA02	Ongoing	Double-blind randomized	IIa & IIb	30%	Mar 6, 2019	Sep 6, 2019	Sep 6, 2020
20000101	SAP TMC E2E 01	BI 811874	Ongoing	Double-blind randomized	IIb	110%	Feb 2, 2019	Aug 2, 2019	Aug 2, 2020

**EPIC CTSM-9**  
Create Study Master for Protocol(s)  
**CTS-M-520**  
As a Trial Manager, I want to edit an existing Study so that I can change the belonging attributes if I need to adapt the study.  
**EPIC CTSM-457**  
As a Trial Manager, I want to have access to the study creation wizard so that I can create a study on my entry page directly.  
**CTS-M-515**  
As a Trial Manager, I want to navigate from my Study List to the Study Details, so that I get view and maintain the Study attributes.

**Object Page (Details of Study) - Create Mode**

**EPIC CTSM-9**  
Create Study Master for Protocol(s)  
**CTS-M-463**  
As a Trial Manager, I want to assign External IDs to my Study Master, so that it is linked to the following systems: CTMS ID, IRT, EudraCT, NCT, other registers

**CTS-M-459**  
As a Trial Manager, I want to create a basic study master object with some header data, so that I can see the created object in my system and continue to work on it afterwards.

**CTS-M-460**  
As a Trial Manager, I want to assign Cost Objects to my Study Master so that controlling is able to report on the costs.

**Study 20000109**

**Study Header**

Study Header	IRT	Contacts	Countries	Study Structure	Study Matrix	Site Events
<b>General Data</b>						
Study ID:	(Earliest) First Patient First Visit: 2020-10-01					
Study Description:	(Latest) Last Patient First Visit: 2020-10-01					
Study Type:	(Latest) Last Patient Last Visit: 2020-10-01					
WBS:	Enrollment Curve: Medium					
Cost Center:	EudraCT: 2020-10-01-02					
Blinding Scenario:	External Distribution Network:					

**CTS-M-515**  
As a Trial Manager, I want to navigate from my Study List to the Study Details, so that I get view and maintain the Study attributes.  
**CTS-M-185**  
As Trial manager, I want to be able to assign a default enrollment curve on study master level so that I could derive the influx of patient enrolment.

**CTSM-462**

As a Trial Manager, I want to assign a Blinding Scenario to my Study Master so that production is executed accordingly.

Pack type	Distribution Network:
Oncology	Fisher
Study Status:	Central Packaging Location:
New	DE20
Study Phase:	Auto Demand:
II	
Clinical Version:	
1.0	

**CTSM-200**

As a Trial Manager, I want to select a Distribution Network and my system to be able to auto populate the default distribution parameters based on the network chosen in the study header so that we can have a complete distribution network assigned with the agreed parameters.

**CTSM-530**

As a Trial Manager, I want to select the IRT provider for my study so that I can get IRT data into my study.

IRT Provider:	Catalent
IRT Trigger Visit:	2
Enrolment Threshold:	20%
Duration until Trigger Visit:	
First Milestone Visit:	2
Actual Start:	

**CTSM-493**

As a Trial Manager, I want to delete a contact from my study master so that it reflects changes responsibility.

**CTSM-464**

As a Trial Manager, I want to assign Contacts with their respective roles and delegates to my Study Master so that it is clear who is responsible for the study in different aspects.

User ID	Name	Role	Phone Number	Email Address	Messenger	Delegated
U3942	Tina Tafani	Clinical Trial Manager	+1-541-754-3010	tina.tafani@email.com	<Messenger URL>	Sam Tucker
U2744	Susan Shen	Supply Chain Planner	+1-541-754-3008	susan.shen@email.com	<Messenger URL>	Elisabeth Leonard
U3664	Daniel Denisson	Distribution Planner	+1-541-754-3006	daniel.denisson@email.com	<Messenger URL>	Robert Michaels
U2449	Clark Clegg	Warehouse Clerk	+1-541-754-3004	clark.clegg@email.com	<Messenger URL>	Dana Parker
U3127	Pablo Paoletti Pereira	Production Manager	+1-541-754-3002	pablo.paoletti.pereira@email.com	<Messenger URL>	Marcia Braziel

**CTSM-483**

As a Trial Manager, I want to delete a contact from my study master so that it reflects changes responsibility.

**CTSM-465**

As a Trial Manager, I want to assign Contacts with their respective roles and delegates to my Study Master so that it is clear who is responsible for the study in different aspects.

**CTSM-497**

As a Trial Manager, I want to be able to define a messenger URL for contacts so that I can easily contact them in case I need to discuss something with them.

**CTSM-501**

As a Trial Manager, I want to maintain additional contacts for a role so that I'm able to contact these delegates in case the primary contact is not available.

**CTSM-502**

As a Trial Manager, I want to be able to define an e-mail address for contacts so that I can easily contact them in case I need to discuss something with them.

**CTSM-481**

As a Trial Manager, I want to delete a country from my study master so that I can unassign a previously added country.

**CTSM-474**

As a Trial Manager, I want to add country lines (empty) to my Study Master so that I can later on plan my demand on country level.

**CTSM-475**

As a Trial Manager, I want the system to provide me with the regulatory approval status per depot so that I can see whether it is allowed to ship the material to the related country.

**CTSM-661**

As a Trial Manager, I want to be able to maintain if a country is active or inactive so that I can later on plan my demand on country level.

**CTSM-485**

As a Trial Manager, I want to delete a Treatment Group from my study master so that I can adapt the Treatment Group assignments accordingly.

**CTSM-465**

As a Trial Manager, I want to create Treatment Groups in my study master so that I can later on assign them in the treatment matrix accordingly.

**CTSM-270**

As a Trial Manager, I want to maintain cohorts so that I can define demand starting points for different treatment groups.

**CTSM-489**

As a Trial Manager, I want to delete a treatment period in my study master so that I can unassign a previously added treatment period.

**CTSM-469**

As a Trial Manager, I want to define Treatment Periods in my study master so that I can assign them later in the treatment matrix.

**CTSM-482**

As a Trial Manager, I want the system to automatically create a new material master for CPG for different countries so that we can avoid manual tasks.

**CTSM-466**

As a Trial Manager, I want to add Packtypes in my study master so that I can later on plan my demand accordingly.

**CTSM-250**

As a Trial Manager, I would like to have the materials linked to search and select existing materials based on certain attributes so that I can assign them to a pack type in my study.

**CTSM-468**

As a Trial Manager, I want to define Treatments in my study master so that I can assign them later on in the treatment matrix.

**CTSM-490**

As a Trial Manager, I want to delete Treatments from my Study Master, so I can unassign previously added treatments.

**EPIC CTSM-482**

Maintain Contacts in Study Master

**CTSM-495**

As a Trial Manager, I want to select existing users and assign them as contacts to my Study Master so that it's clear who is responsible for the study in different aspects.

**CTSM-494**

As a Trial Manager, I want to be able to define a role for contacts so that I know the responsibility of this person in case I need to discuss something with them.

**CTSM-507**

As a Trial Manager, I want to be able to define a phone number for contacts so that I can easily contact them in case I need to discuss something with them.

**EPIC CTSM-471**

Maintain Countries in Study Master

**CTSM-472**

As a Trial Manager, I want to assign Countries to my Study Master so that I can later on plan my demand on country level.

Country	Region	Depot	Label Group	Depot to Site Delivery Lead Time	Status	Regulatory Approval	FFPV
Australia	Pacific	40057349	M1	20 days	Active	✓	Oct 20, 2019 Apr 2
Canada	North America	40038643	M1	11 days	Inactive	✓	Oct 20, 2019 Apr 2
Germany	Europe	40011274	M1	8 days	Active	✓	Oct 20, 2019 Apr 2
France	Europe	40027673	M1	8 days	Active	✓	Oct 20, 2019 Apr 2
United States	North America	40090832	M1	9 days	Active	✓	Oct 20, 2019 Apr 2
East	North America	40012211	M1	13 days	Active	✓	Oct 20, 2019 Apr 2
West	North America	40012211	M1	9 days	Active	✓	Oct 20, 2019 Apr 2

**CTSM-251**

As a Trial Manager, I want to maintain the Delivery Lead Times for each site so that I could consider them when I do my demand forecasting.

**EPIC CTSM-484**

Maintain Treatment Groups in Study Master

**CTSM-473**

As a Trial Manager, I want to get default values for Region and Depot proposed from the system, once I select a country so that I can review these values and change them if required afterwards.

**CTSM-251**

As a Trial Manager, I want to maintain the Delivery Lead Times for each site so that I could consider them when I do my demand forecasting.

**EPIC CTSM-488**

Maintain Treatment Periods in Study Master

**CTSM-472**

As a Trial Manager, I want to maintain Material Number per Country, and per Packtype in my study master so that I can later on plan my demand accordingly.

Treatment Period ID	Treatment Period Description	Cohort	Number of Repetitions	Duration	Dosage	Dosage Coverage	Break Unit
Period05	6x1 month		6	Month	1.00	0.00	
Period04	6x1 month		6	Month	1.00	0.00	
Period03	6x1 month		6	Month	1.00	0.00	
Period02	1x1 month		1	Month	1.00	0.00	
Period01	1x1 month		1	Month	1.00	0.00	

**EPIC CTSM-478**

Maintain Pack Types in Study Master

**CTSM-478**

As a Trial Manager, I want to maintain the Material Number per Country, and per Packtype in my study master so that I can later on plan my demand accordingly.

Pack Type ID	Pack Type Description	Status	Australia	Canada	Germany	France	United States
KIT3	Active 200mg double blind	Active	190	1193	1190	1190	1193
KIT2	Active 200mg double blind	Active	1189	1192	1189	1189	1192
KIT1	Active 0mg double blind	Active	1188	1191	1188	1188	1191

**EPIC CTSM-487**

Maintain Treatments in Study Master

**CTSM-478**

As a Trial Manager, I want to maintain the Material Number per Country, and per Packtype in my study master so that I can later on plan my demand accordingly.

Treatment ID	Treatment Description	Number of Units	Pack Type	Pack Type Description
Treatment04	Active 400mg	2	KIT3	Active 200mg double blind
Treatment03	Active 200mg	1	KIT3	Active 200mg double blind
Treatment03	Active 200mg	1	KIT1	Active 0mg double blind
Treatment02	Active 100mg	1	KIT2	Active 100mg double blind
Treatment02	Active 100mg	1	KIT1	Active 0mg double blind
Treatment01	Active 0mg	2	KIT1	Active 0mg double blind

**EPIC CTSM-493**

Maintain Study Matrix

Treatment Group 1 (High Dosage)	Prescreening Treatment Period 1		Core Treatment Period 1		Core Treatment Period 2		Core Treatment Period 3		Core Treatment Period 4		Core Treatment Period 5	
	1x1 month		1x1 month		1x1 month		6x1 month		6x1 month		6x1 month	
Treatment01 0mg	Treatment01 0mg		Treatment02 100mg		Treatment03 200mg		Treatment04 400mg		Treatment04 400mg		Treatment04 400mg	
Treatment Group 2 (Medium Dosage)	Treatment01 0mg		Treatment02 100mg		Treatment03 200mg		Treatment03 200mg		Treatment03 200mg		Treatment03 200mg	
Treatment	Treatment01 0mg		Treatment02 100mg									

**CTSM-464**  
As a Trial Manager, I want to unassign treatments from treatment group + treatment period combination so that I can later on plan my demand accordingly.

**CTSM-467**  
As a Trial Manager, I want to assign treatments to treatment group + treatment period combination so that I can later on plan my demand accordingly.

**Site Events**

**Materials (15)**

Material ID	Material Description	Country	Apr 12, 2020	May 31, 2020
1188	Active 0mg	Australia		
1189	Active 100mg	Australia		15
1190	Active 200mg	Australia		
1191	Active 0mg	Canada	13	
1192	Active 100mg	Canada		
1193	Active 200mg	Canada		
1188	Active 0mg	Germany		15
1189	Active 100mg	Germany		
1190	Active 200mg	Germany	13	
1188	Active 0mg	France		
1189	Active 100mg	France		
1190	Active 200mg	France		15
1191	Active 0mg	United States		
1192	Active 100mg	United States	13	
1193	Active 200mg	United States		

**CTSM-608**  
As a Trial Manager, I want to be able to save a draft during creation of the study and come back later so that I can interrupt my work any time and finish it later.

## Object Page (Details of Study) - Create Mode - Countries II

**Study 20000109**

Study Header    IRT    Contacts    **Countries**    Study Structure    Study Matrix    Site Events    Show Demand Plan

**Depot Assignment:**

- Assignment at Country Level
- Assignment at Country & Pack Type Level

**Label Group Assignment:**

- Assignment at Country Level
- Assignment at Country & Pack Type Level
- Assignment at Country & Pack Type Level

**CTSM-536**  
As a Trial Manager, I want to be able to assign and overview the enrollment information on the individual country level so that I could derive the influx of patient enrolment.

**Countries (5)**

Country	LPFV	Actual Patients	Enrolment Threshold	Over Enrolment	Planned Enrolment	Add	Delete	Collapse All	Search
Australia	2020		20%	18	180	Low	0%	0%	Yes
Canada	2020		20%	10	100	Low	0%	0%	Yes
Germany	2020		20%	10	100	Low	0%	0%	Yes
France	2020		10%	9	90	Power Factor 2	0%	0%	Yes
United States	2020		10%	10	100	Low	0%	0%	No
East	2020		10%	4	40	Medium	0%	0%	No
West	2020		10%	6	60	Low	0%	0%	No
<b>Sum</b>				<b>57</b>	<b>570</b>				

**Study Structure**

**Treatment Groups (4)**

Treatment Group ID	Treatment Group Description	Patient Ratio	Overage	Cohort	Shift	Shift Unit
TG04	Placebo (active 0mg double blind)	1			Day	
TG03	Low dosage (active 100mg double blind)	1			Day	
TG02	Medium dosage (active 200mg double blind)	1			Day	

Draft saved    Save    Create Matrix    Cancel

No labels