



New ePRISM Features Released 9.Dec.2015

Section – General

1.	Roche Logo	Roche logo now appears in the upper left-hand corner of application.
2.	Calendar Tab Removed	There is no longer a calendar view in ePRISM.
3.	Changed 'Feedback' link to 'Support'	Links in each colorbar used to be labeled 'feedback' are now labeled 'support'.
4.	Improved the Support Dialog	When you click the 'support' link, the modal window that opens has been improved.
5.	Email comes from ePRISM@staffready.com	Email notifications that are sent from ePRISM are now from the email address ePRISM@staffready.com .



Section – Response Tab

6.	Removed Department Task Report	There is no longer a department task report within the Response tab.
7.	Changed 'Subject' to 'Study Leader'	Column within the Response tab previously labeled 'Subject' is now labeled 'Study Leader'.
8.	Changed 'Document' to 'Study Task'	Column within the Response tab previously labeled 'Document' is now labeled 'Study Task'.
9.	Added 'Type' column	There is a new column within the Response tab labeled 'Type'.
10.	Added 'Anticipated Inspection Question' column	There is a new column within the Response tab labeled 'Anticipated Inspection Questions'.
11.	Added 'Items to be Considered' column	There is a new column within the Response tab labeled 'Items to be Considered'.
12.	Added ability to see priority with color (BLUE, P3)	Response Owner tasks that are priority three will now display in the Response tab with blue highlight.

Response
Create PRISM
Study Leader

Roche Response Reports

Employee ePRISM Task Report

[Support](#) [Help](#)

Employee

Brigitte Saroka [change](#)

Date Range*

[this year](#) [this month](#) [this week](#) [custom](#)

02-Jun-2015 - 02-Jun-2016

Show Only Overdue Tasks

On/Off

Employee Task Report

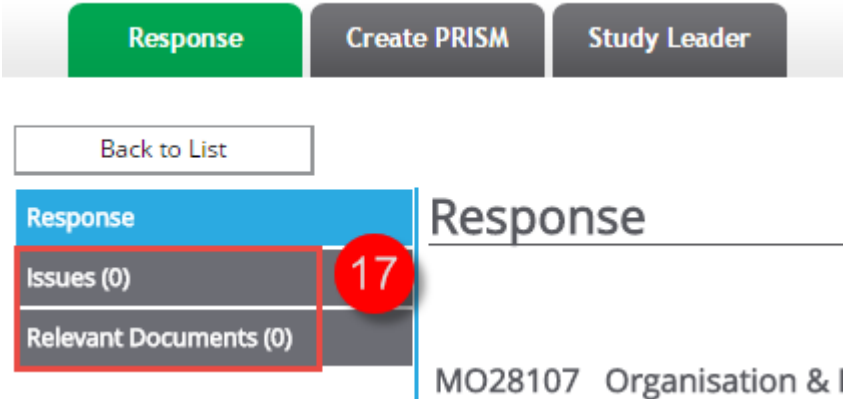
Brigitte Saroka (02-Jun-2015 - 02-Jun-2016)

Status	Assignment Period	Study Leader	Study Task	Type	Anticipated Inspector Questions / Request for Information	Items to be Considered
! Overdue (22-Jul-2015)	21-Apr-2015 - 21-Jul-2015	Dimitri Messeri	MO28107 - I.2	Response Owner	Obtain relevant organizational charts that document structure and responsibilit...	EACH functional area is re to provide their organizat chart upon requ...
! Overdue (22-Jul-2015)	21-Apr-2015 - 21-Jul-2015	Dimitri Messeri	MO28107 - I.3	Response Owner	(1) Identify all departments, functions, and key individuals responsible for are...	Communication channel of the inspection needs to be agreed upon with the SM...
! Overdue (22-Jul-2015)	21-Apr-2015 - 21-Jul-2015	Dimitri Messeri	MO28107 - I.7	Response Owner	The independence of the Quality Assurance Unit	
! Overdue (22-Jul-2015)	21-Apr-2015 - 21-Jul-2015	Dimitri Messeri	MO28107 - III.5	Response Owner	Identify any investigators who didn't comply with regulations.	List to be prepared ad ho Inspectors will investigate determine whether stu...
! Overdue (22-Jul-2015)	21-Apr-2015 - 21-Jul-2015	Dimitri Messeri	MO28107 - III.6	Response Owner	Determine how compliance was secured and Show Evidence of	As mentioned above, che written evidence of corre...

13. Removed the red






There are no longer response owner tasks highlighted in red within the Response tab.



14.	Click Working Task or Action Item, Shows Study No.	The study number now appears within the task completion screen for working tasks and action items.
15.	'Email All' now shows all	After selecting 'Email All' within the Response tab, the Email All modal will display all of the email recipients.
16.	Ability to edit completed tasks, while in Preparation	Completed tasks are now able to be edited before the study is moved out of the preparation phase.
17.	Numbers now appear in the Response Dialog Side Tab	Within the corresponding side tab menu of the Response dialog, numbers now appear indicating the total number of issues and relevant documents. 



Section – Create PRISM Tab

18.	Load: “none” for department	After clicking Load button, the Department field lists ‘None’.
19.	Load: Cannot select location if not in your dept.	After clicking the change link under Department and selecting a location, the location options are limited to department locations of the chosen department.
<div style="text-align: center;">Load Template</div> <p>Study Number STUDY BATTERY1</p> <p>Theme STUDY BATTERY1</p> <p>Product STUDY BATTERY1</p> <hr/> <p>Department*  None change 18</p> <p>Study Leader Location*  Choose a department 19</p> <p>Study Leader*  Brigitte Saroka</p> <p>Template*  Choose One</p> <p>Load From Template</p>		
20.	Load: Load confirmation modal after loading	Confirmation appears after clicking Load From Template button. <div style="border: 1px solid gray; padding: 10px;"><div style="background-color: black; color: white; padding: 5px;">Load Study ✕</div><div style="margin-top: 10px;"> Are you sure you want to load the study 'STUDY BATTERY1' with the 'gRED' template? It will be loaded into the 'gRED' department with 'Administrator ePRISM' as the study leader.</div><div style="margin-top: 10px;">Confirm Cancel</div><div style="text-align: right; margin-top: 20px;">WICKET AJAX DEBUG</div></div>



21.	Global department removed from tree	Global department no longer appears within the View By Department perspective of the Create PRISM tab.
22.	Email Response Owners	Email Response Owners link now available in the header of selected study. Selecting link opens Email Response Owners modal which allows current response owners of the study to be emailed directly from ePRISM.
23.	Study: CTMS data added to header	CTMS information now appears in the header of selected modal, including: Theme, Product, Study Leader, and Location.
24.	Warning dialog when changing between states	When clicking on a status change button in the header of a study, the Change Study Status modal will open.

The screenshot displays the ePRISM interface for study BH21260. At the top, there are buttons for 'Response', 'Create PRISM', and 'Study Leader'. Below these is a 'View By Department' dropdown menu and a search bar. The study header shows 'BH21260 Preparation [30-Sep-2015 ends 30-Dec-2015]' with buttons for 'Change to Extension', 'Change to Review Window', and 'Email Response Owners'. Below the header, study details are listed: 'Theme - 3264 | Product - MIRCERA | Study Leader - Ngoc-Phuong Cecile Coralie Nguyen Becker | Location - Basel'. A 'Change Study Status' modal dialog is open, showing 'Changing to Extension' and a message: 'Changing to extension is just an extended preparation phase. Tasks will remain active.' The dialog has 'Save Changes' and 'Cancel' buttons.

25.	Warning on Unload	After clicking to unload a study, the unloading of the study is more comprehensive and now unloads accountable role teams.
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26.	Assign Owners: Export link	Export link allows the study to be exported into an excel spreadsheet.
27.	Assign Owners: Hide priority three questions	Clicking the Hide Extended Questions box will hide questions that are priority three questions.
28.	Assign Owners: Start Inspection (Inspection Mode)	Clicking the Start Inspection button will assign out the priority three questions to response owners.
29.	Assign Owners: Items to be considered added	Added the column Items to be Considered in the Assign Owners colorbar.
30.	Assign Owners: N/A column, adds comment to compliance notes, lined out question text (saved)	Added the column N/A in the Assign Owners colorbar.

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Hide Extended Questions (blue) 27

Section	Anticipated Inspector Questions / Request for Information	Items to be Considered 29	Roles	Response Owner change 31	N/A 30
1	Determine the overall organization of the clinical research activities and monit...	The CSL would e in a strong position to give an overview of the CDP, the OPL wil...	CSL,OPL,GSM	Patricia Wurtz	<input type="checkbox"/>
2	Obtain relevant organizational charts that document structure and responsibiliti...	EACH functional area is required to provide their organizational chart upon requ...	IC,GIG	Brigitte Saroka	<input type="checkbox"/>
3	(1) Identify all departments, functions, and key individuals responsible for are...	Communication channel during the inspection needs to be agreed upon with the SMT...	IC,GIG,GSL	Brigitte Saroka	<input type="checkbox"/>
4	(2) Determine who has authority to approve study reports and study listings	The Drug Regulatory Committee chair or it's delegate can approve clinical study ...	CS,Biostat,Reg	Delphine Oguey	<input type="checkbox"/>
5	(3) Determine who is responsible for final evaluations and decisions in reviewin...	Ensure PV Agreements available for partnered trials and outsourced activities Th...	Safety_S	Ngoc-Phuong Cecile Coralie Nguyen Becker	<input type="checkbox"/>
6	Obtain a list of all monitors (for the studies being inspected) along with their...	GSM to reach out to CSM for support as needed. CTMS is the single source of info...	GSM	Patricia Wurtz	<input type="checkbox"/>

28 28 28

31.	Assign Owners: Click Response Owners Change link	Response Owner change link will open the Edit Response Owners dialog.
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32.	<ul style="list-style-type: none"> Add Response Owner: Check boxes 	Checking box of question is necessary to add new response owner to that question.
33.	<ul style="list-style-type: none"> Add Response Owner: Filter 	Search filters allow for questions to be searched/filtered based on Response Owner, Anticipated Inspector Questions, Items to be Considered, and Roles criteria.
34.	<ul style="list-style-type: none"> Add Response Owner: Add Button 	After entering employee name in text field, the Add button allows the employee to be added to selected questions.

Edit Response Owners

Add Response Owners

Add Response Owners

Employee:* Add 34

Remove/Replace Response Owners

[select all](#)

	Response Owner	Anticipated Inspector Questions / Request for Information	Items to be Considered	Roles
<input type="text" value="Search"/> <input type="button" value="All"/>	<input type="text" value="Response Owner"/>	<input type="text" value="Anticipated Inspector Questions"/>	<input type="text" value="Items to be Considered"/>	<input type="text" value="Accountable Role"/>
32 <input type="checkbox"/>	I.1 Patricia Wurtz	Determine the overall organization of the clinical research activities and monit...	The CSL would e in a strong position to give an overview of the CDP, the OPL wil...	CSL,OPL,GSM
<input type="checkbox"/>	I.2 Brigitte Saroka	Obtain relevant organizational charts that document structure and responsibiliti...	EACH functional area is required to provide their organizational chart upon requ...	IC,GIG
<input type="checkbox"/>	I.3 Brigitte Saroka	(1) Identify all departments, functions, and key individuals responsible for are...	Communication channel during the inspection needs to be agreed upon with the SMT...	IC,GIG,GSL
<input type="checkbox"/>	I.4 Delphine Oguey	(2) Determine who has authority to approve study reports and study listings	The Drug Regulatory Committee chair or it's delegate can approve clinical study ...	CS,Biostat,Reg
<input type="checkbox"/>	I.5 Ngoc-Phuong Cecile Coralie Nguyen Becker	(3) Determine who is responsible for final evaluations and decisions in reviewin...	Ensure PV Agreements available for partnered trials and outsourced activities Th...	Safety S
<input type="checkbox"/>	I.6 Patricia Wurtz	Obtain a list of all monitors (for the studies being inspected) along with their...	GSM to reach out to CSM for support as needed. CTMS is the single source of info...	GSM



35.	<ul style="list-style-type: none"> Remove/Replace: Employee field and Filter button Remove/Replace: Replace With text field and Replace button 	Employee field allows for response owners to be searched in order to find questions currently assigned. Replace With field allows for employees to be selected to replace the existing response owner.
36.	<ul style="list-style-type: none"> Remove/Replace: Checkboxes 	Selects the question to replace and/or remove the existing response owner.
37.	<ul style="list-style-type: none"> Remove/Replace: Filter text boxes 	Search filters allow for questions to be searched/filtered based on Response Owner, Anticipated Inspector Questions, Items to be Considered, and Roles criteria.

Edit Response Owners

Add Response Owners

Remove/Replace Response Owners

Remove/Replace Response Owners

Employee:*

Brigitte Saroka

Remove

35

Replace With:

Replace

Reset

select all	Response Owner	Anticipated Inspector Questions / Request for Information	Items to be Considered	Roles
<input type="checkbox"/>	I.2 Brigitte Saroka	Obtain relevant organizational charts that document structure and responsibiliti...	EACH functional area is required to provide their organizational chart upon requ...	IC,GIG
<input type="checkbox"/>	I.3 Brigitte Saroka	(1) Identify all departments, functions, and key individuals responsible for are...	Communication channel during the inspection needs to be agreed upon with the SMT...	IC,GIG,GS
<input type="checkbox"/>	I.7 Brigitte Saroka	The independence of the Quality Assurance Unit		IC,GIG
<input type="checkbox"/>	X.1 Brigitte Saroka	Determine record retention procedures/policies (paper & electronic)	Should cover system for archiving and retrieval of documents Control access to t...	IC



38.	Roles: Click link	Click roles link to open Edit Accountable Roles dialog.
39.	<ul style="list-style-type: none"> Role Side Tab: Append Response Owners mode 	Allows new response owners to be added to selected questions.
40.	<ul style="list-style-type: none"> Role Side Tab: Overwrite Response Owners mode 	Allows new response owners to replace existing response owners for selected questions.
41.	<ul style="list-style-type: none"> Role Side Tab: Add team member link 	Opens Add Employee dialog which allows new team members to be added to the selected accountable role.
42.	<ul style="list-style-type: none"> Role Side Tab: Check boxes, select all 	Allows questions to be selected in order to indicate which questions the accountable role change should be made.
43.	<ul style="list-style-type: none"> Role Side Tab: Filter text boxes 	Search filters allow for questions to be searched/filtered based on Response Owner, Anticipated Inspector Questions, Items to be Considered, and Roles criteria.
44.	<ul style="list-style-type: none"> Role Side Tab: Apply button 	Completes the append/overwrite of response owners for the selected questions.

Edit Accountable Roles

CSL

CSL

OPL

Members of the CSL Team

GSM

[add team member](#) 41

Mode*

Append Response Owners 39

Overwrite Response Owners 40

44

[select all](#) 42

43

<input type="checkbox"/>	I.1 Patricia Wurtz	Determine the overall organization of the clinical research activities and monit...	The CSL would e in a strong position to overview of the CDP, the OPL wil...
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45.	Study Tasks: Priority Three tasks now Blue	Priority three questions now appear as highlighted in blue.
46.	Maintenance Mode: Ability to move from Ready to Preparation, no longer have to go to Draft, allows for reopening of questions, not a new version	Ability to move from Ready to Preparation, without having to go to Draft. Allows for reopening of questions without creating a new version.

Section – Study Leader Tab

47.	Added GIG Report	Within the Study Leader or Department perspective, there is a new GIG Report.
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Response
Create PRISM
Study Leader

View By Department

PD/Dev

[Support](#) [Help](#)

Enter your search...

Go

GIG Report

[Download Excel Report](#)

	Study Number	Study Leader	Product	Status	Assigned Questions	Completed Questions	N/A Questions
<div style="border: 1px solid #ccc; padding: 2px 5px; font-size: 0.7em;">Search</div> <div style="margin-top: 5px;"> <input style="width: 100%; border: none; border-bottom: 1px solid #ccc;" type="text"/> </div>	<input style="width: 100%; border: none; border-bottom: 1px solid #ccc;" type="text"/>	<input style="width: 100%; border: none; border-bottom: 1px solid #ccc;" type="text"/>	<input style="width: 100%; border: none; border-bottom: 1px solid #ccc;" type="text"/>	<div style="border: 1px solid #ccc; padding: 2px 5px; font-size: 0.7em;">All Statuses</div>			
	BH21260	Ngoc-Phuong Cecile Coralie Nguyen Becker	MIRCERA	Preparation (30-Sep-2015)	✓ 79/79 (100%)	⚠ 21/79 (27%)	0
	BN29739	Henry Bennett	OCRELIZUMAB	Preparation (16-Sep-2015)	✓ 101/101 (100%)	⚠ 7/101 (7%)	0
	BO17929	Amanda Liddle	Perjeta	Draft (05-Jan-2015)	⚠ 94/118 (80%)	🔒 In Draft	7
	BO20652	Mariette Schlegel	Herceptin	Draft (24-Mar-2015)	⚠ 70/126 (56%)	🔒 In Draft	0
	BO20924	Alice Palmer	Avastin	Draft (28-Jan-2015)	⚠ 97/101 (96%)	🔒 In Draft	0
	BO21000	Kirstie Meldrum	GAZYVA	Draft (02-Jun-2015)	⚠ 90/123 (73%)	🔒 In Draft	0
	BO21005	Kirstie Meldrum	GAZYVA	Preparation (28-Aug-2015)	✓ 127/127 (100%)	⚠ 6/127 (5%)	0

Prepared by Maplewood Software for Roche

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