

# **Group Informatics**

## **User Manual**

*[Clinical Research Metrics Dashboard]*

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<b>Solution Owner</b>	Michael Zhang
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## Document History

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## 1. Purpose

The purpose of this document is to introduce functionality that has provided in the system and instruct users using that functionality properly and effectively.

## 2. Definitions

The following terms and abbreviations are used in this document:

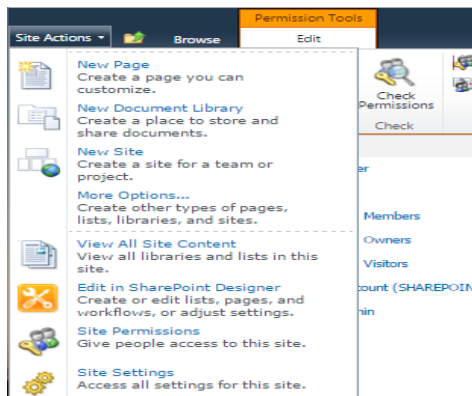
Term	Definition
LM	Line Manager
CPL	Clinical Project Leader
Admin	Administrator

## 3. Operation: Admin

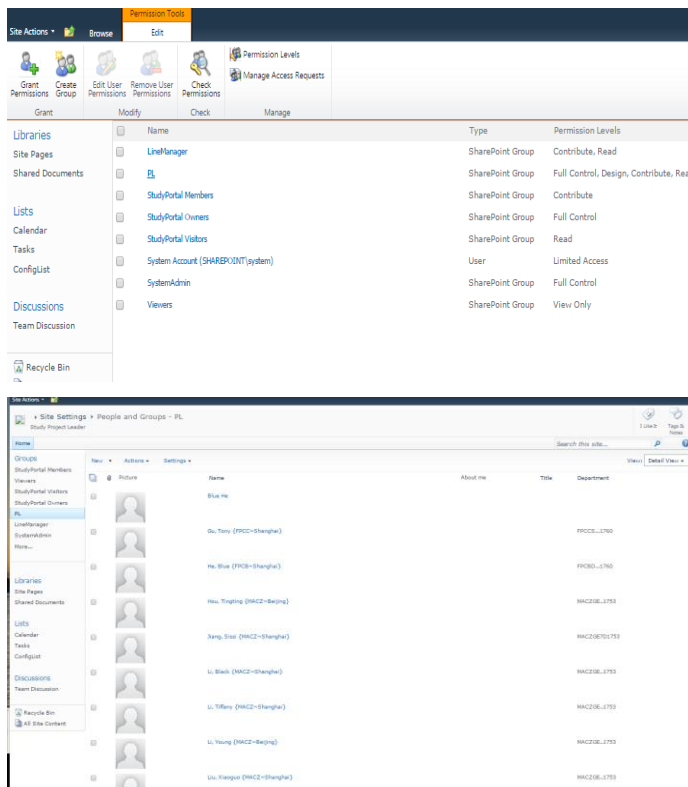
System administrator can maintain permission of CPL, LM to the Clinical Research Metrics Dashboard.

### 3.1 Add CPL or LM users

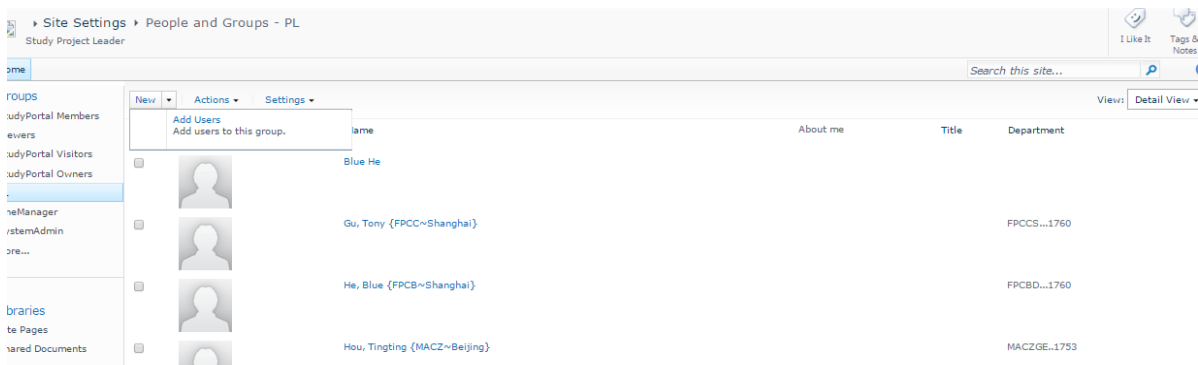
1. Access Administration address:  
<http://spdeweb01.shp.roche.com/sites/StudyPortal/SitePages/Forms/AllPages.aspx>
2. Click on "Site Actions" on the top of left, then click on "Site Permission"



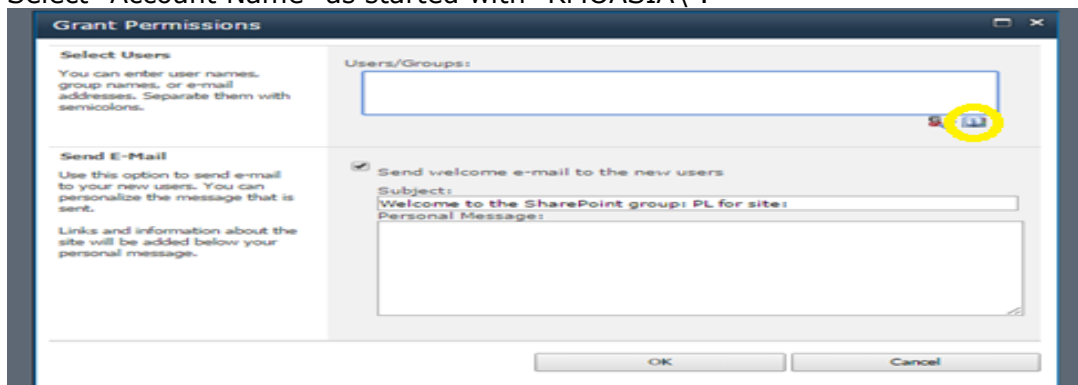
3. Click on "PL" or "LM" to access "PL" or "LM" group

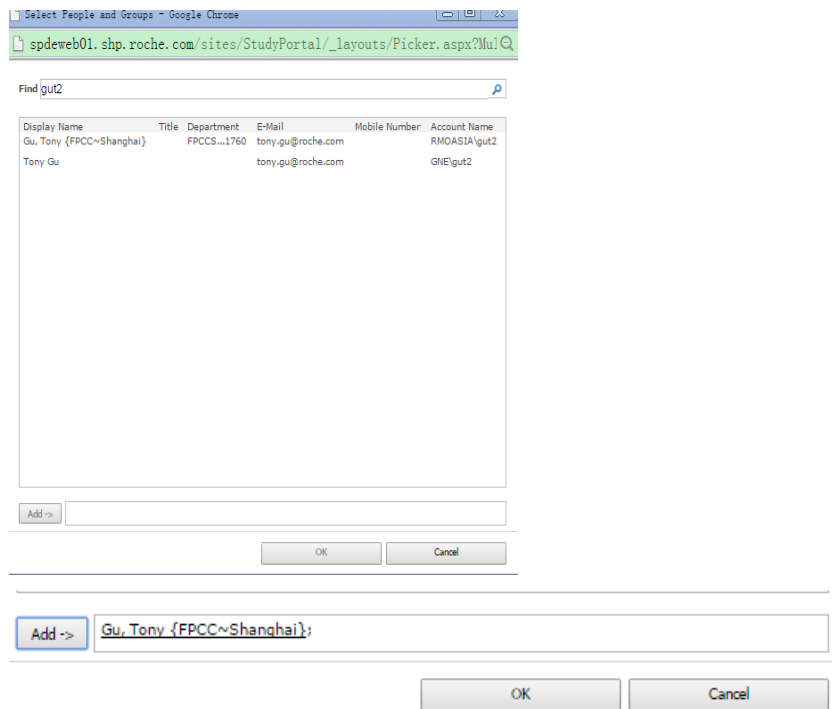


#### 4. Click "New", click "add users"



#### 5. Click on "bookmark", In "Find" area, input userid, click on "search" button on the right, Select "Account Name" as started with "RMOASIA\".

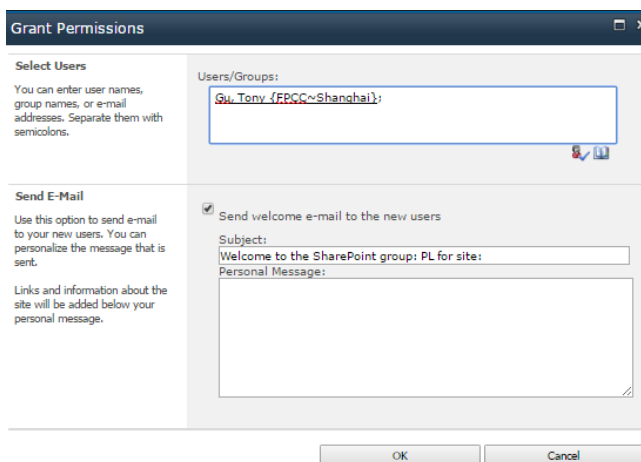




Display Name	Title	Department	E-Mail	Mobile Number	Account Name
Gu, Tony {FPCC~Shanghai}		FPCCS...1760	tony.gu@roche.com		RMOASIA\gut2
Tony Gu			tony.gu@roche.com		GNEI\gut2

Add ->  OK Cancel

6. Click "Add" button, click "OK" button.



Select Users

You can enter user names, group names, or e-mail addresses. Separate them with semicolons.

Users/Groups:

Gu, Tony {FPCC~Shanghai}:

Send E-Mail

Use this option to send e-mail to your new users. You can personalize the message that is sent.

Links and information about the site will be added below your personal message.

☒ Send welcome e-mail to the new users

Subject:

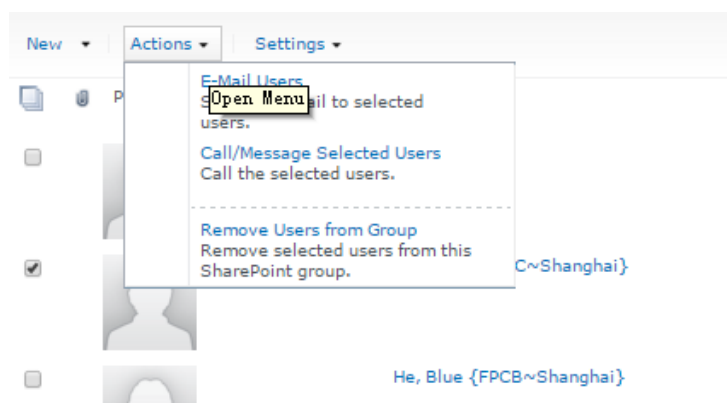
Welcome to the SharePoint group: PL for site:

Personal Message:

OK Cancel

## 3.2 Remove CPL or LM users



1. Repeat Step 1-3 in Add users.
2. Select a user, click on Actions, then click "Remove users from group"



### 3.3 Assign New Incoming Study to CPL

If there is a new incoming study detected from CTMS, Clinical Research Metrics Dashboard system will send notification mail to portal administrator, administrator should assign this new study to a responsible CPL.

- Access study link in notification mail, and access SMT Chart page.
- Click "Add" button to add responsible CPL.
- Click "save" to save changes.

--Status--	--Roles--	--CompanyType--	<div>SAVE ADD EXPORT</div>						
Image	IsOwner	Domain Name	Name	Role	Roche/Sponsor/CRO	Company Name	Start Date	End Date	Comment
 Edit			tyy	Data Manager	Roche	ddd	2015-10-01		
 Edit		RMOASIA\GUT2	333	CPL	Roche	33	2015-10-31		2321

**Note:** IsOwner means CPL member who is in charge of new study, change the value to "Yes", and input the "Domain Name" as "RMOASIA\userid"(ex, RMOASIA\GUT2)

## 4. Operation: CPL

CPL (Clinical Project Leader) can maintain assigned studies information on Clinical Research Metrics Dashboard.

### 4.1 Access Home Page

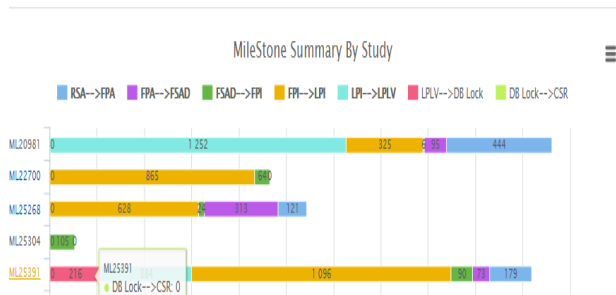
On Home Page, CPL can see assigned studies summary.

<http://spdwweb01.shp.roche.com/sites/StudyPortal/SitePages/HomePage.aspx>

#### 4.1.1 Milestone Summary by Study

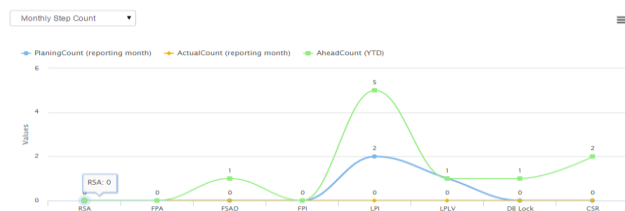
Display duration between two consecutive Milestones



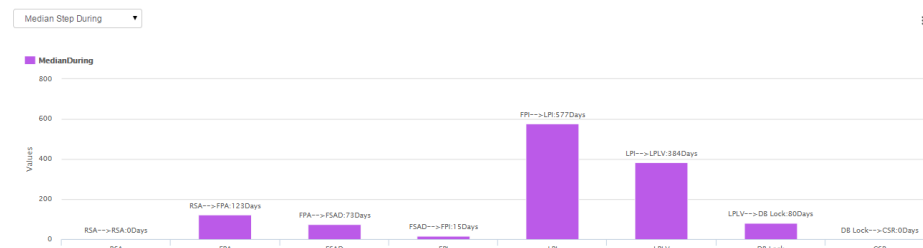


### 4.1.2 Monthly Step Count/ Median Step During

- a. Planning count (Reporting Month), Actual count (Reporting Month), Ahead count(YTD) is counts of Actual date < Planned date at each milestone level.

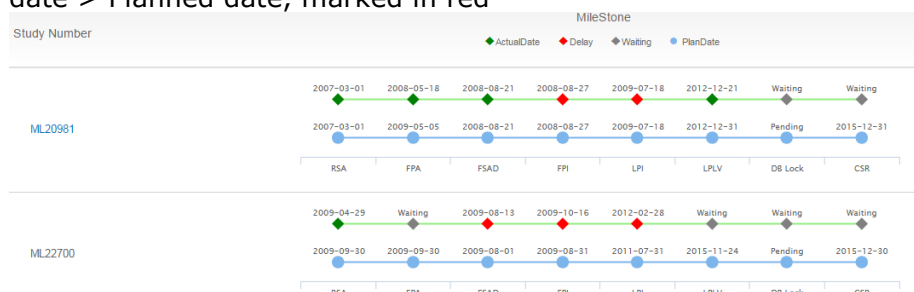


- b. Click on arrow to view Median Step During, which means the median duration days between two consecutive milestone



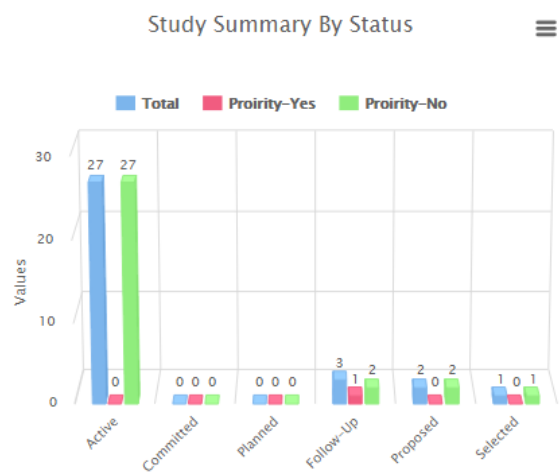
### 4.1.3 Study Milestone details

Display Study Milestone details, If Actual date <= Planned date, marked in green, If Actual date > Planned date, marked in red



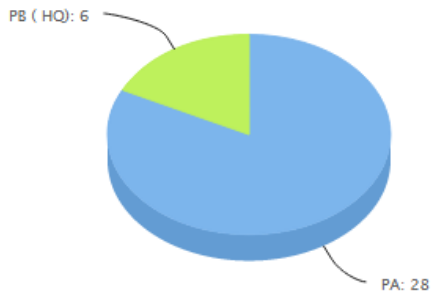
### 4.1.4 Study Summary by Status

Display counts of Study by different status and priority.



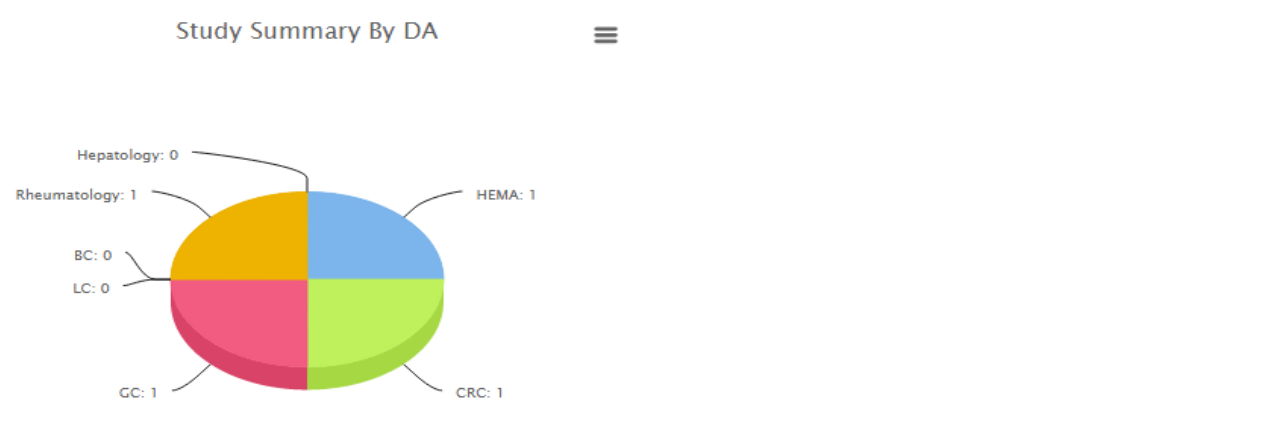
### 4.1.5 Study Summary by GPS

Display counts of Study by GPS  
Study Summary By GPS



### 4.1.6 Study Summary by DA

Display counts of Study by DA



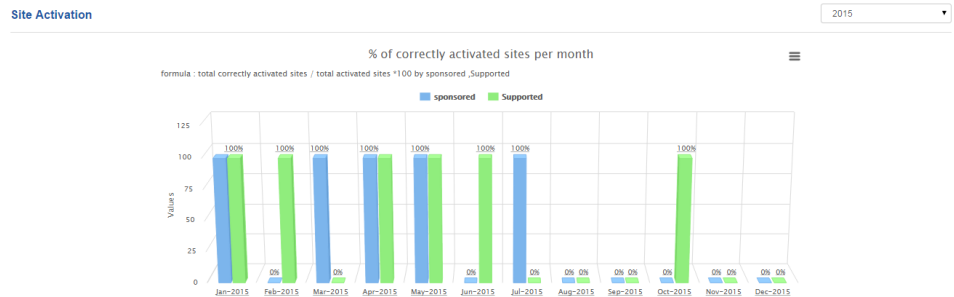
4.1.7 Study Summary by Interventional

Display counts of Study by Interventional



4.1.8 Site Activation

Display % of correctly activated sites per month.  
Formula: Corrected active sites/total activated sites



4.1.9 Recruitment

Display Enrollment Speed by Study  
Formula:

% enrollment speed: Cumulative Actual/Cumulative Planning

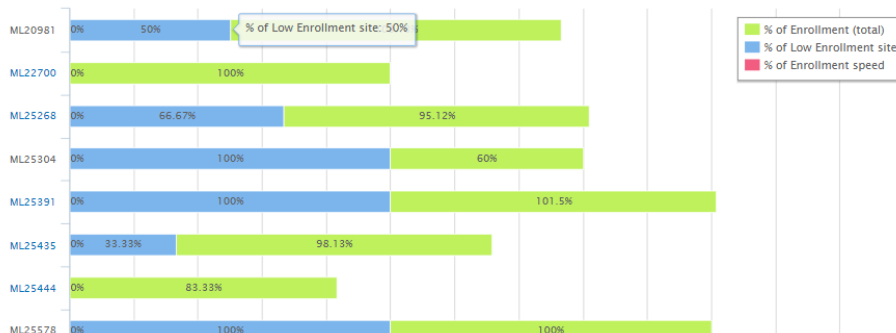
% enrollment (total): SCNTR\_ACTUALNUMENROLLED/PLANNEDNUMENROLLED

% low enrollment site: Low percent counts of site /Total counts

#### Recruitment

Enrollment Speed by Study

formula: %Enrollment Speed (total) = cumulative actual / planned total target \* 100, % Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100, % of low enrollment site = number of low enrollment site / total selected sites \* 100, low enrollment site is site with enrollment speed <=80%



### 4.1.10 ICF

Display % of correctly approved ICFs

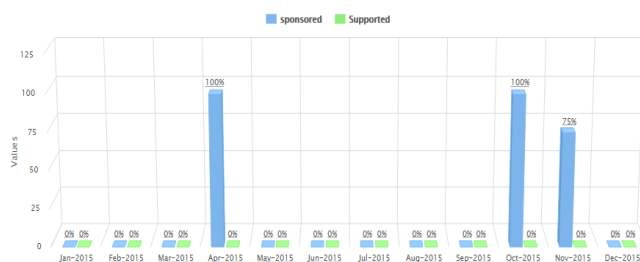
Formula: Correctly approved ICFs/total ICFs

#### ICF

2015

% of corrected Approved ICFs

formula : total correct approved ICFs / total ICFs \*100 by sponsored ,Supported



### 4.1.11 Issue Log

Display % of delayed issues per month

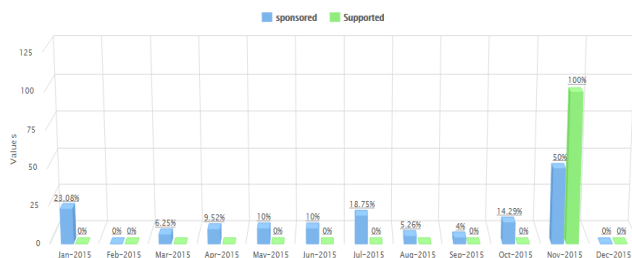
Formula: Delayed issues/Total issues

#### Issue Log

2015

% of delayed issues per month

formula : total delayed issues / total issues \*100 by sponsored ,Supported



### 4.1.12 Trial Monitor

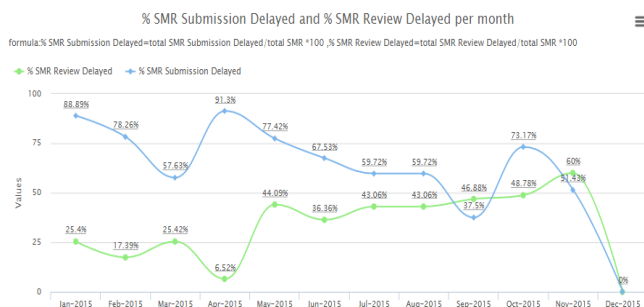
Display % SMR submission delayed and % SMR review delayed per month

Formula:  $\text{SMRReviewDelay} = \text{DelaySToRCount} / \text{TotalCount}$

$\text{SMRSubmissiondelay} = \text{DelayCToSCount} / \text{TotalCount}$

[Trial Monitor](#)

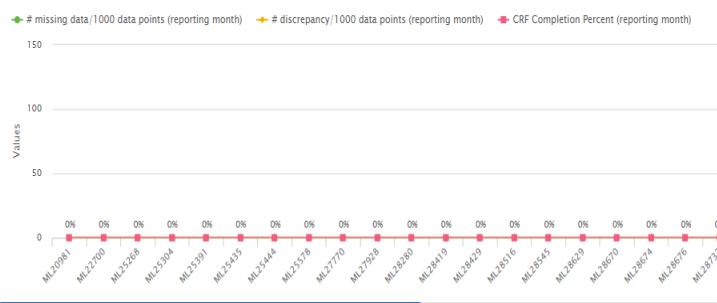
2015



### 4.1.13 CRF

Display # missing data/1000(reporting month), # discrepancy data/1000(reporting month), CRF completion %

[CRF](#)



### 4.1.14 Safety Reference

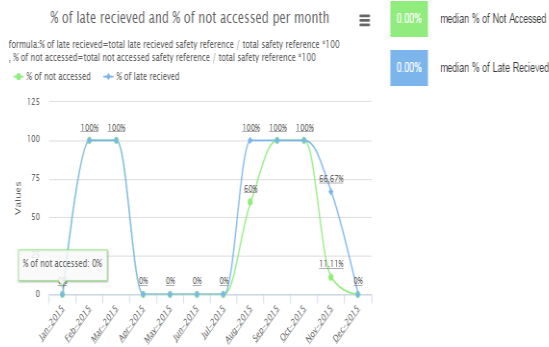
Display % of late received and % of not accessed per month

Formula: 1) % of "Not Accessed" for each site = number of "not accessed" / number of all documents (removed document is excluded).

2) % of late received for each site = number of late received document / number of all documents, late received means the time between the "date document was first accessed by the site" and "document upload date" is larger than 14 calendar days.

## Safety Reference

2015



## 4.2 Overview Page

Overview page display single detailed study information, CPL can check /uncheck filter to display relevant information.

### Overview of Study

☐ ALL ☒ General Information ☒ Country Timeline ☒ Site Timeline Median Duaring ☐ Site Activation ☐ CRF ☐ ICF ☐ Safety Reference ☐ Issue Log ☐ Recruitment ☐ Trial Monitor

### 4.2.1 General information

Display General Information for current study, user can maintain "DA", "Priority" area if necessary, and click save to save changes.

#### General Information

Study No.	ML25304	Country Status	Active	Revised Planned # Site	17
Product	Cisplatin,Tarceva,Vials containing powder for solution for infusion.	Executing Party	Investigator	Actual # Site	14
DA *	Rheumatology	Accountable Roche Party	PA	Revised Planned # Enrolled	90
Interventional Study	Yes	Priority *	No	Actual # Enrolled	54
Study Short Title	Neoadjuvant T vs GC in IIIA-N2 NSCLC with EGFR(+)				
Comment	<div></div>				
<div>SAVE</div>					

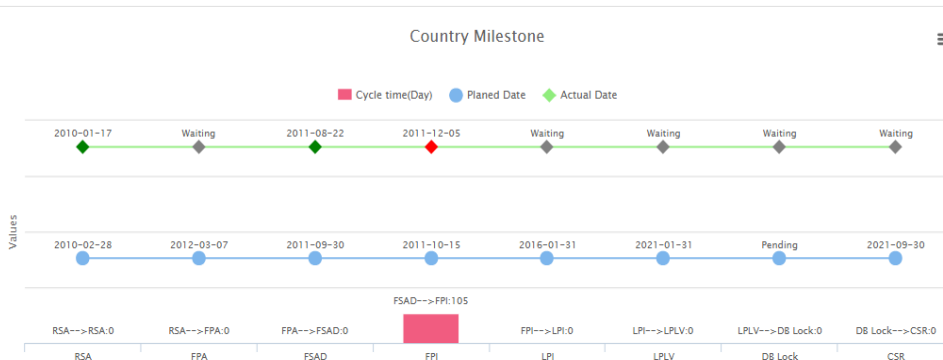
### 4.2.2 Country Timeline

Display current study of Country Milestone

Formula:

Cycle Time=duration days between two consecutive milestones, If actual date > planned date, highlight the milestone with red.

## Country Timeline



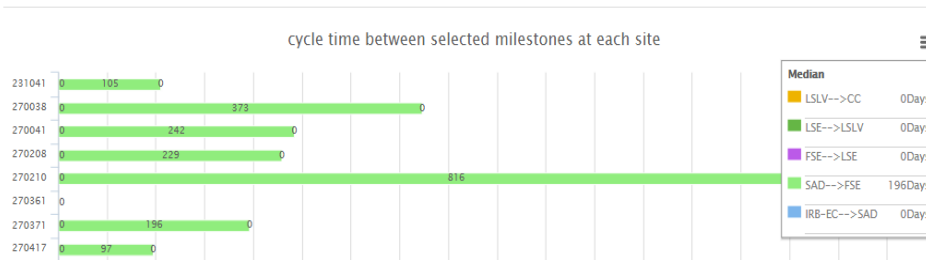
### 4.2.3 Site Timeline Median Duration

Display current study of Cycle time between selected milestones at each site.

Formula:

Duration days between two consecutive milestones

[Site Timeline Median Duration](#)



### 4.2.4 Recruitment

Display current study of Country level enrollment Progress

Formula:

% of enrollment (total) = cumulative actual / planned total target \* 100

Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100

% of low enrollment site = number of low enrollment site / total selected sites \* 100

low enrollment site is site with enrollment speed <=80%

## Recruitment

% of enrollment (total) = cumulative actual / planned total target \* 100%

30.62%

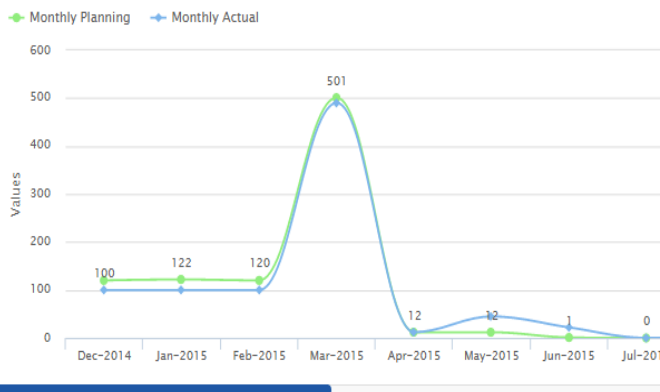
Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100

90.17%

% of low enrollment site = number of low enrollment site / total selected sites \* 100%, low enrollment site is site with enrollment speed <=80%

100%

### Country Level Enrollment Progress

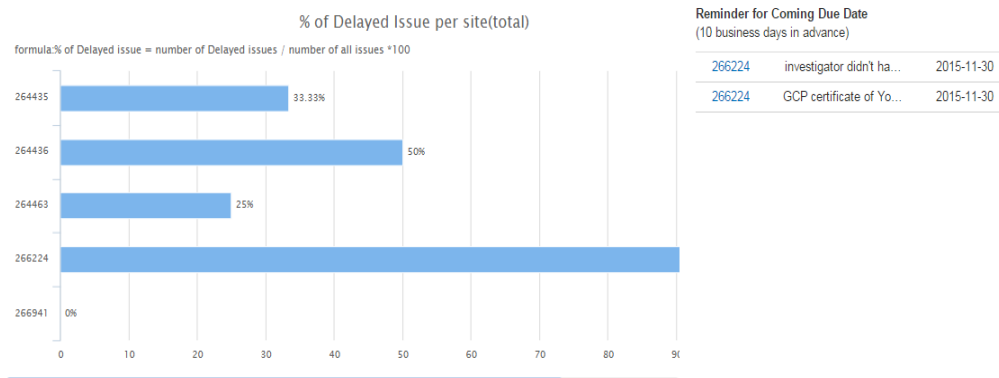


## 4.2.5 Issue log

Display current study of % of delayed issues per site (total), and the "Reminder for Coming Due Date" displayed on the right.

Formula: 10 Business days reminder for coming due date

### Issue Log



## 4.2.6 Trial Monitoring

Display current study of SMR review delayed and % SMR submission delay per month

Formula:

% of SMR Submission Delay in the reporting month (Date Submitted falls in the reporting month) = number of "Comp. - Sub." >5 / number of submitted SMR \* 100

% of SMR Review Delay in the reporting month (Date Reviewed falls in the reporting month) = number of "Sub. - Rev." >5 / number of reviewed SMR \* 100



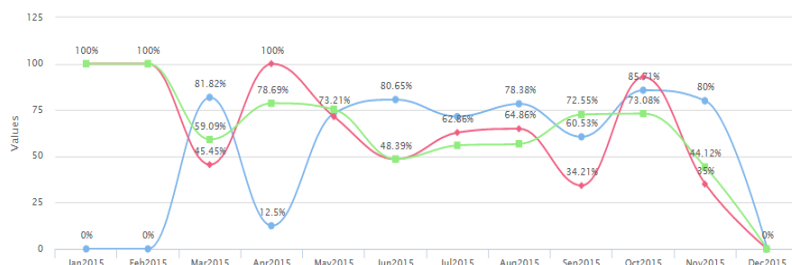
## Trial Monitor

2015

% SMR Review Delayed and % SMR Submission Delay per Month

% SMR Review Delayed=total SMR Review Delayed/total SMR\*100, % SMR Submission Delayed=total SMR Submission Delayed/total SMR\*100, % Completed Trial Monitor=total Completed Trial Monitor/total Trial Monitor\*100

◆ % SMR Review Delayed ◆ % SMR Submission Delayed ◆ % Completed Trial Monitor



## 4.2.7 Safety Reference

Display current study of % of not accessed and % of late received by site

Formula:

1) % of "Not Accessed" for each site = number of "not accessed" / number of all documents (removed document is excluded).

2) % of late received for each site = number of late received document / number of all documents, late received means the time between the "date document was first accessed by the site" and "document upload date" is larger than 14 calendar days.

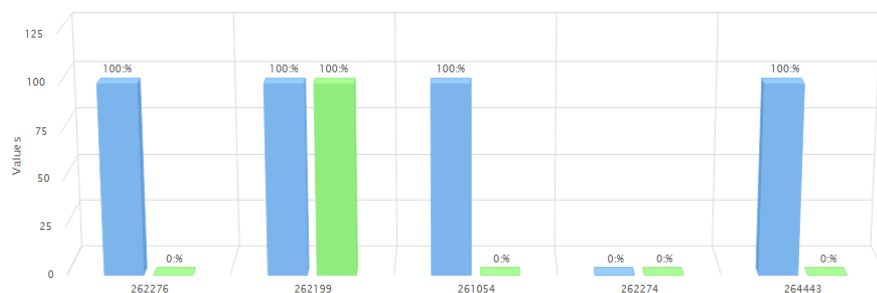
Note: Doc. Rec by Site-Doc. Sub. Date>14

## Safety Reference

% of Not accessed and % of Late Received by Site

formula: % of Not Accessed for each site = number of not accessed / number of all documents, % of late received for each site = number of late received document / number of all documents

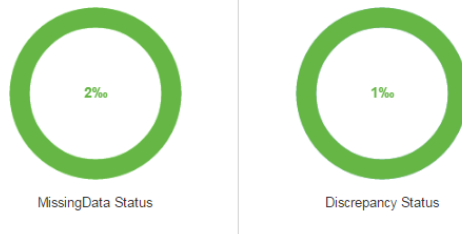
■ % Not accessed(Median:100%) ■ % Late Received( Median:0%)



## 4.2.8 CRF

Display current study of Missing Data status and Discrepancy status

CRF



### 4.2.9 Site Activation

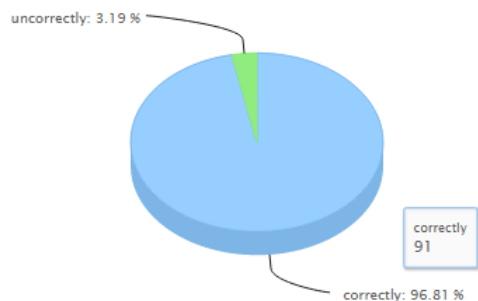
Display % of correctly activated sites for current study

Formula: % of correctly activated sites = number of correctly activated site / number of total activated site \* 100, correctly activated site is site activated with the completion of "site selection checklist" and " green light approval for site activation"

[Site Activation](#)

% correctly activated

% of correctly activated sites = number of correctly activated site / number of total activated site \* 100%




### 4.2.10 ICF

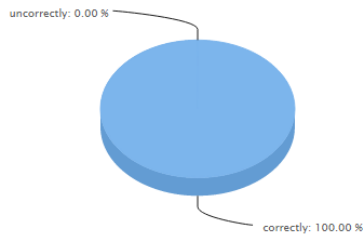
Display % correctly approved sites for current study

Formula: % of ICFs which correctly approved for each month, ICF which correctly approved means the "gcp\_for004222" is OK status.

## ICF

% correctly approved(reporting month) 

% of ICFs correctly approved = number of correctly approved ICFs/number of ICFs \* 100%



## 4.3 Time Line

### 4.3.1 Country Time Line

Display Country timeline details

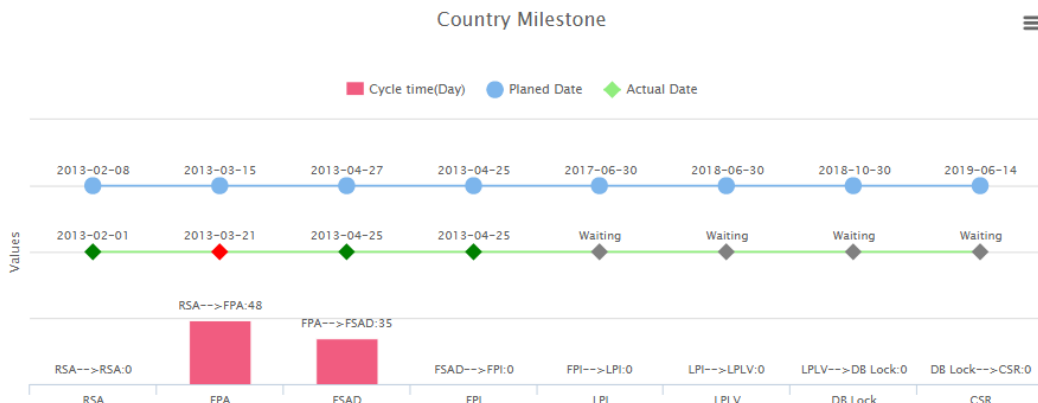
Setting: if actual date > planned date, highlight the milestone with red

Data Analysis: duration days between two consecutive milestones, then get the bar chart

#### Country Timeline

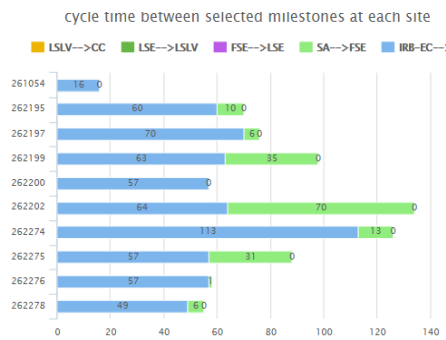
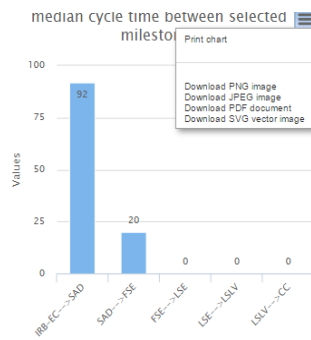
Key milestones at country and site level are captured here (all data from CTMS, no manual entry is required).

Metric: Cycle time (measured in days) between two consecutive milestones. Long cycle times could indicate that the site should try to identify areas where the process is delayed. The point's color of delay milestone will be marked with 'red'

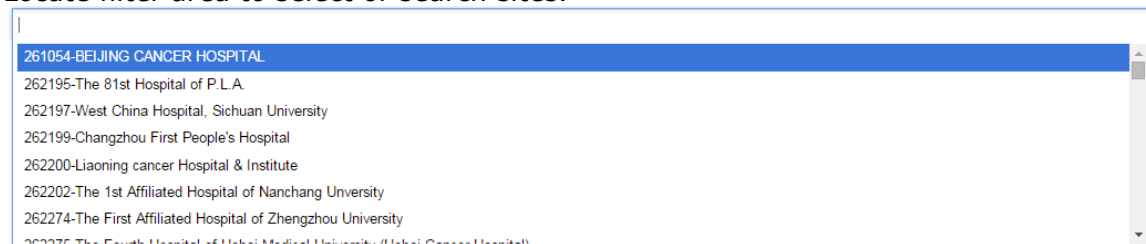


### 4.3.2 Site Time Line

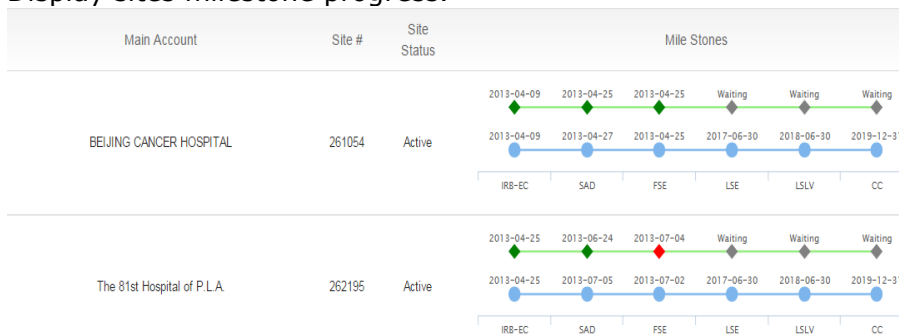
- Display "Median cycle time between selected milestones"
- Display "Cycle time between selected milestones at each site"
- Click "Print Picture" button to download chart as different format



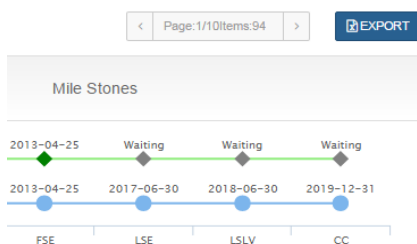
d. Locate filter area to select or search sites.



e. Display sites milestone progress.



f. Click "Export" to export Time Line, and generate excel file



g. CPL can locate downloaded excel for more detailed data.

The screenshot shows an Excel spreadsheet titled 'SiteMilestone (1).xls'. The table has the following data:

Site #	Site Name	Site Status	IRB/EC Approval (Plan)	IRB/EC Approval (Actual)
261054	BEIJING CANCER HOSPITAL	Active	2013/4/9	
262195	The 81st Hospital of P.L.A.	Active	2013/4/25	
262197	West China Hospital, Sichuan University	Active	2014/6/30	
262199	Changzhou First People's Hospital	Active	2013/11/5	
262200	Liaoning cancer Hospital & Institute	Active	2013/11/18	
262202	The 1st Affiliated Hospital of Nanchang University	Active	2013/6/25	
262274	The First Affiliated Hospital of Zhengzhou University	Active	2013/7/10	
262275	The Fourth Hospital of Hebei Medical University (Hebei Cancer	Active	2013/7/3	

## 4.4 SMT Chart



CPL can maintain SMT chart

d. Click "Arrow" button on filter area to filter Status/Roles/Company type.

--Status-- --Roles-- --CompanyType--

- e. Click "Add/Edit" button to add/edit team member, if select "Sponsor or CRO" in Roche/Sponsor/CRO field, please input "Sponsor/CRO" name.
- f. If "End" Date is blank, the image highlight as "blue", if "End" Date is added, the image highlight as "grey".
- g. Click "save" to save changes.

--Status-- --Roles-- --CompanyType-- SAVE ADD EXPORT

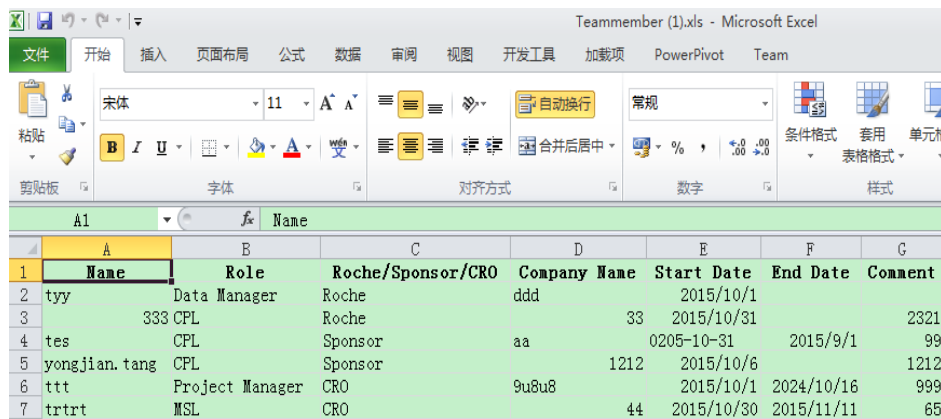
Image	IsOwner	Domain Name	Name	Role	Roche/Sponsor/CRO	Company Name	Start Date	End Date	Comment
			tyy	Data Manager	Roche	ddd	2015-10-01		
		RMOASIA\GUT2	333	CPL	Roche	33	2015-10-31		2321

**Note:** IsOwner means backup team member who is also in charge of current study as backup role, by default, the value is "No". If you want assign a backup member, change the value to "Yes", and input the "Domain Name" as "RMOASIA\userid"(ex, RMOASIA\GUT2)

h. CPL can click "Export" to export team members, and generate excel file.



i. Open exported excel file to view data.

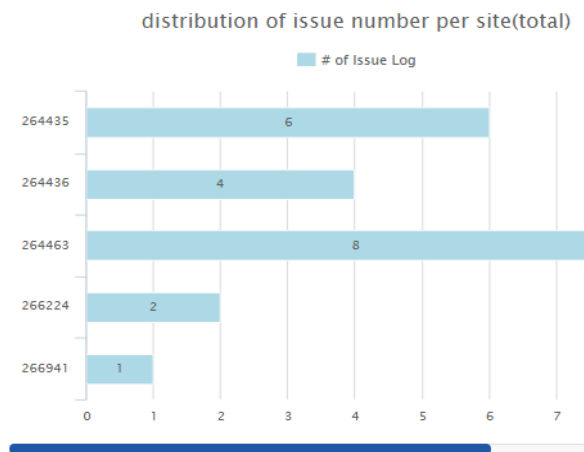


The screenshot shows a Microsoft Excel spreadsheet titled 'Teammember (1).xls'. The ribbon includes '文件', '开始', '插入', '页面布局', '公式', '数据', '审阅', '视图', '开发工具', '加载项', 'PowerPivot', and 'Team'. The '开始' ribbon is active, showing options for font, alignment, and styles. The spreadsheet contains a table with the following data:

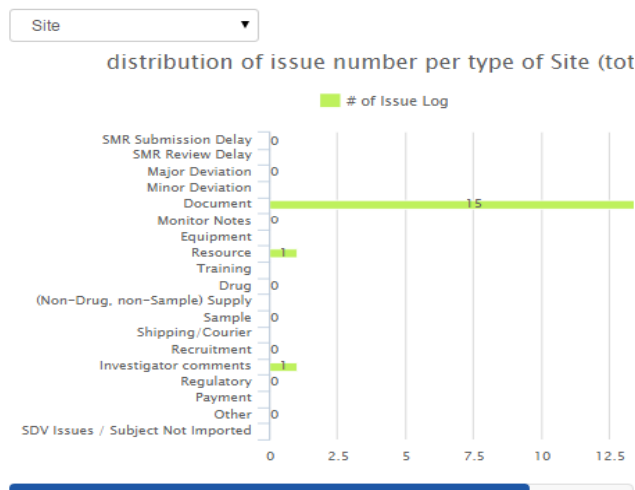
	A	B	C	D	E	F	G
1	Name	Role	Roche/Sponsor/CRO	Company Name	Start Date	End Date	Comment
2	tyy	Data Manager	Roche	ddd	2015/10/1		
3	tes	333 CPL	Roche	33	2015/10/31		2321
4	yongjian.tang	CPL	Sponsor	aa	0205-10-31	2015/9/1	99
5	ttt	Project Manager	Sponsor	1212	2015/10/6		1212
6	trtrt	MSL	CRO	9u8u8	2015/10/1	2024/10/16	999
7				44	2015/10/30	2015/11/11	65

## 4.5 Issue Log

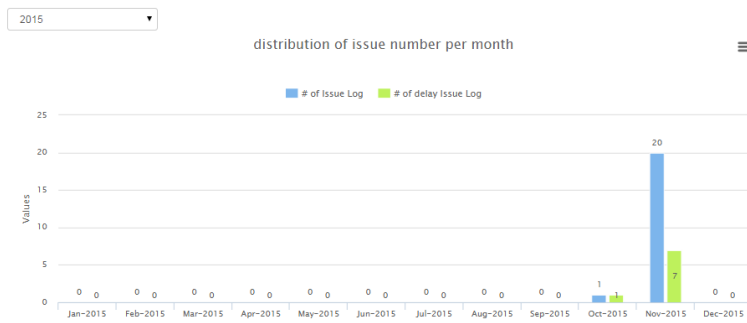
### a. Display "Distribution of issue number per site(total)"



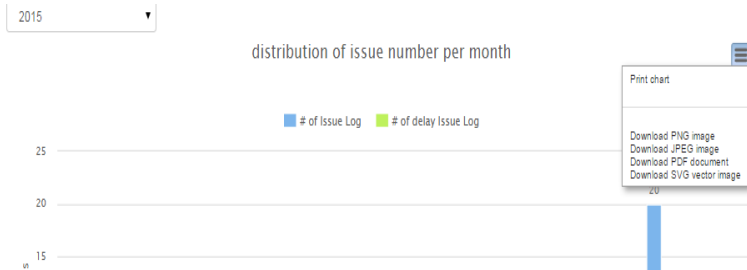
### b. Display "Distribution of issue number per type of site(total)"



### c. Display "Monthly issue log summary"



d. Click "Print Picture" button to download chart as different format



e. Click "Add" button or "Site#" to add/modify issue log, click ok to save changes.

f. Note: when select Site or Subject, the issue type selection list should be changed according to the type.

1/10

low Num: 10    -Subject    -Issue:    < Page:1/3Items:21 >    +ADD    EXPORT

Site #	Account Name	Site Status	Site or Subject	Issue Type	Description	Planned Action	Resolution
264435	Fujian Medical Unive...	Active	Site	Document	The newsletters, wer...	SM to print the newsl...	CRA filed in
264435	Fujian Medical Unive...	Active	Site	Document	2014 local lab certific...	CRA will collect from ...	SN collected th
264435	Fujian Medical Unive...	Active	Site	SDV Issues/Subject N...	ICF process of subje...	CRA to confirm with i...	CRA communic
264435	Fujian Medical Unive...	Active	Site	Document	Qiuping Huang's dele...	CRA to confirm with ...	PI ended the di
264435	Fujian Medical Unive...	Active	Site	SDV Issues/Subject N...	ICF process of Subje...	CRA to confirm with i...	CRA confirmed
264435	Fujian Medical Unive...	Active	Site	Document	All of the SI's GCP c...	CRA will collect SI d...	CRA collected f

Site # 264435-Fujian Medical University Union Hospital    Site Name Fujian Medical University Union Hospital

Site Status Active    Site or Subject Site

Issue Type Document    Issue Status Closed

Observation Date 2015-10-14

Due Date 2015-11-11    Completed Date 2015-11-11

Description  
The newsletters, weren't filed in ISF.

Planned Action  
SM to print the newsletter and send to CRA, CRA to file in ISF during this visit.

Resolution  
CRA filed in ISF

OK

g. Rule Setting in table

Reminder: 10 business days before Due Date, highlight "Due Date" with yellow  
 Delay: completed date > due date, highlight the "Completed date" with red

Due Date	Comp. Date
2015-11-27	
2015-11-20	
2015-11-13	
2015-11-20	
2015-11-30	
2015-11-30	

h. Click "Export" to export Issue Log data as excel file



j. Open excel file to view detailed data

Site #	Account Name	Site Status	Site or Subject	Issue Type
264435	Fujian Medical University Union Hospital	Active	Site	Document
264435	Fujian Medical University Union Hospital	Active	Site	Document
264435	Fujian Medical University Union Hospital	Active	Site	SDV Issues/Subject Not Imported

## 4.6 Case Report Form

Display and maintain monthly CRF completion status.

a. CPL can input current month of discrepancy, missing data, completion value.

Date	% discrepancy	% missing data	% Completion	Comments	Discrepancy Status	MissingData Status	Completion Status
Dec-2015	30	10	1		30%	10%	1%

Note:

if # of discrepancy/1000 data points >100, highlight with red

if # of missing data/1000 data points >200, highlight with red; if >=100 and <=200, amber

CRF completion percent <= 80%, highlight with red

b. Click save to save record.

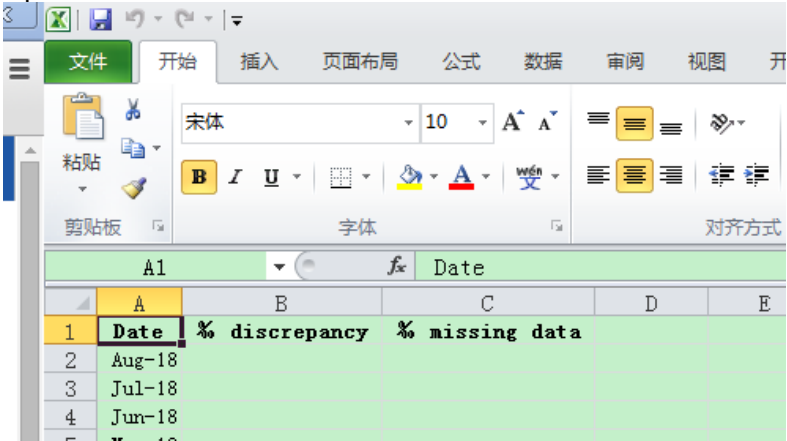




c. Click "Export" to export Case Report Form data as excel file



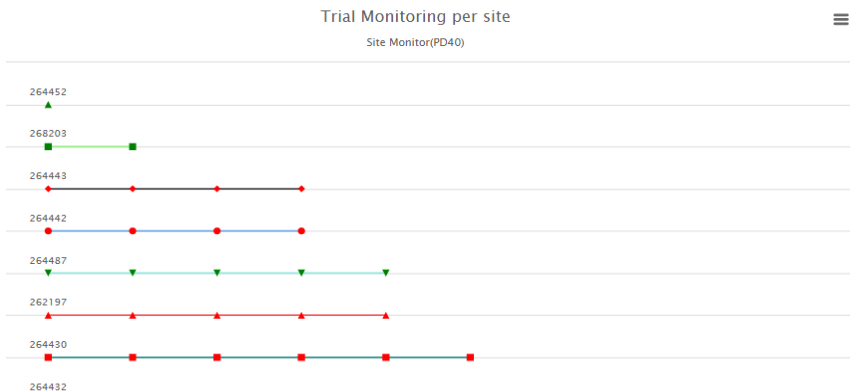
d. Open excel file to check CRF data.



## 4.7 Trial Monitoring

Display "Trial Monitoring per site", "maintain On-site Monitoring Frequency", "maintain Trial Monitoring data table".

a. Display Trial Monitoring per site.



Formula: Green in chart: Activity Start Date of PD40 in the range of Earliest Trial Date and Latest Trial Date

Red in chart: Activity Start Date of PD40 out the range of Earliest Trial Date and Latest Trial Date

b. Maintain "On-site Monitoring Frequency" , manually input frequency, click save to save records, then click generate plan to update Earliest Trial Date and Latest Trial Date.

On-site Monitoring Frequency SAVE GENERATE PLAN

Frequency Type	Earliest Trial Interval	Latest Trial Interval	Frequency Unit	Comments
FPI->1stPD40	1	3	Weekly	<div>history</div>
FPI->LPI	2	3	Monthly	<div>history</div>
LPI->LPLV	2	3	Weekly	<div>history</div>
LPLV->CSR	1	3	Weekly	<div>history</div>

- c. In the table, manually maintain "CPL confirm", and "CPL comments", "Monitor comments", click save to save changes.

CPL confirm	CPL Comments	Reset Plan	Monitor Comments
<div></div>	<div></div>	<div></div>	<div></div>
<div></div>	<div></div>	<div></div>	<div></div>
<div></div>	<div></div>	<div></div>	<div></div>

- d. Check traffic light in data table.

Formula: if  $\text{Comp-Sub}(\text{SubmittedDate-ACD})/\text{Sub.-Rev}(\text{DateReviewed-SubmittedDate}) > 10$ , red;  $10 \geq$  and  $> 5$ , yellow.

Submitted Date	Comp. - Sub.	Report Status	Date Reviewed	Sub. - Rev.
2013-05-23	28	Reviewed	2013-05-23	0
2015-03-11	42	Reviewed	2015-03-11	0
	0	Planned		0
2015-05-22	7	Reviewed	2015-05-30	8

- e. Click "Export" to export Case Report Form data as excel file



- f. Open excel file to check data.

Site #	Site Name	Site Status	Activity Type	Communication Type
1	261054 BEIJING CANCER HOSPITAL	Active	Site Pre-Activation (PD30)	
2	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
3	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
4	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
5	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
6	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
7	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
8	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
9	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
10	261054 BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	

## 4.8 Site Activation

Maintain site activation records.

- a. Locate a record, and click on drop down arrow for SSC or GLA, change its status, click save to save change.

Site Name	Site #	Site Status	SSC	IRB/EC	SCA	GLA	SAD
BEIJING CANCER H...	261054	Active	No	2013-04-09	2013-04-19	Yes	2013-04-25
The 81st Hospital of ...	262195	Active	Yes	2013-04-25	2013-04-25		2013-06-24
West China Hospital...	262197	Active	No	2014-07-02	2014-09-05	No	2014-09-10



Note:

Setting: If ("Site Selection Checklist"="No" and "IRB/EC approval" is not blank/-), alert "Site Selection Checklist (SSC)" is red.

If ("Green Light Approval"="No" and "site activation date" is not blank/-), alert "Green Light Approval (GLC)" is red.

- b. Click "Export" to export team members, and generate excel file.



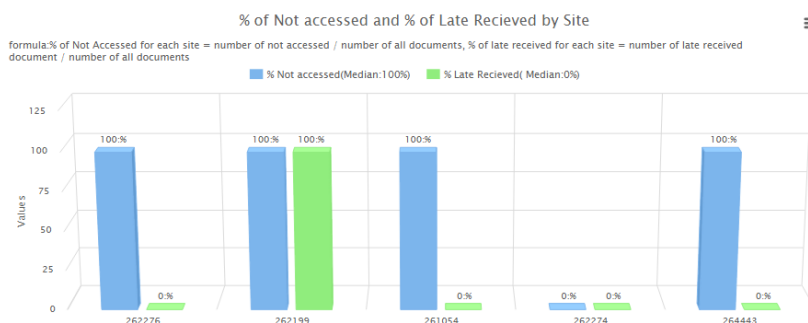
- c. Open excel file to view data.

Site Name	Site #	Site Status	SSC	IRB/EC	SCA	GLA	SAD
BEIJING CANCER HOSPITAL	261054	Active	No	2013/4/9	2013/4/19	Yes	2013/4/25
The 81st Hospital of P.L.A.	262195	Active	No	2013/4/25	2013/4/25		2013/6/24
West China Hospital, Sichuan University	262197	Active	No	2014/7/2	2014/9/5	No	2014/9/10
Changzhou First People's Hospital	262199	Active		2013/11/5	2013/12/31		2014/1/7
Liaoning cancer Hospital & Institute	262200	Active		2013/11/18	2013/12/31		2014/1/14
The 1st Affiliated Hospital of Nanchang University	262202	Active		2013/6/25	2013/8/8		2013/8/28
The First Affiliated Hospital of Zhengzhou University	262274	Active		2013/7/10	2013/10/18		2013/10/31
The Fourth Hospital of Hebei Medical University (Hebei Cancer Hospital)	262275	Active		2013/7/3	2013/8/19		2013/8/29
Liaoning cancer Hospital & Institute	262276	Active		2013/11/18	2013/12/30		2014/1/14

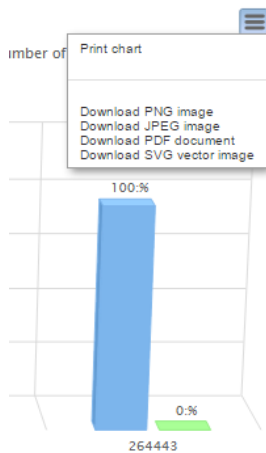
## 4.9 Safety Reference

Display "% of Not accessed and % of late received by site", and maintain Safety Reference records.

- a. Display "% of Not accessed and % of late received by site".



- b. Click "Print Picture" button to test download chart as different format.



- c. Click "Add" or "Edit" button to add/edit a site record, click "Save" to save record

	Site #	Site Name	Doc. Name	Doc. Ver.	Doc. St.
Edit	262276	Liaoning cancer Hos...	11	1	Not Accessed
Edit	262199	Changzhou First Peo...	11	1	Not Accessed
Edit	261054	BEIJING CANCER H...	1	1	Not Accessed
Edit	262274	The First Affiliated H...	21	221	Accessed
Edit	262276	Liaoning cancer Hos...	11	1	Not Accessed
Edit	264443	The First Affiliated H...	11	1	Not Accessed
Edit		BEIJING CANCER H...	1	1	Not Accessed
Edit		The First Affiliated H...	21	221	Accessed
Edit		Liaoning cancer Hos...	11	1	Not Accessed
Edit		Changzhou First Peo...	11	1	Not Accessed
Edit		BEIJING CANCER H...	1	1	Not Accessed
Edit		The First Affiliated H...	21	221	Accessed
Edit		Liaoning cancer Hos...	11	1	Not Accessed

Note: Setting: If "Document Status" = "Not Accessed", highlight with red

- d. Use filter areas to filter sites, for example, click on "-Status-".

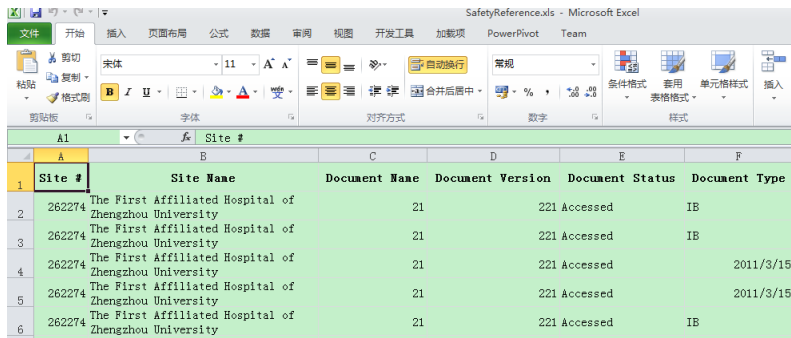
Accessed

	Site #	Site Name	Doc. Name	Doc. Ver.	Doc. St.
Edit	262274	The First Affiliated H...	21	221	Accessed
Edit	262274	The First Affiliated H...	21	221	Accessed
Edit	262274	The First Affiliated H...	21	221	Accessed
Edit	262274	The First Affiliated H...	21	221	Accessed

- e. Click "Export" to export Safety Reference data, and generate excel file

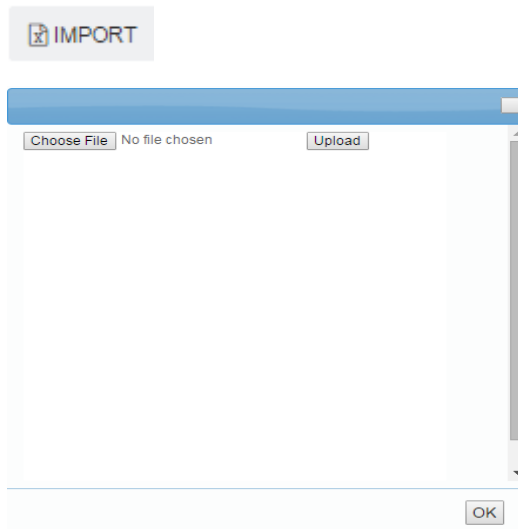


- f. Open excel file to view data.



	A	B	C	D	E	F
	Site #	Site Name	Document Name	Document Version	Document Status	Document Type
1	262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	IB
2	262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	IB
3	262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	2011/3/15
4	262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	2011/3/15
5	262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	IB
6	262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	IB

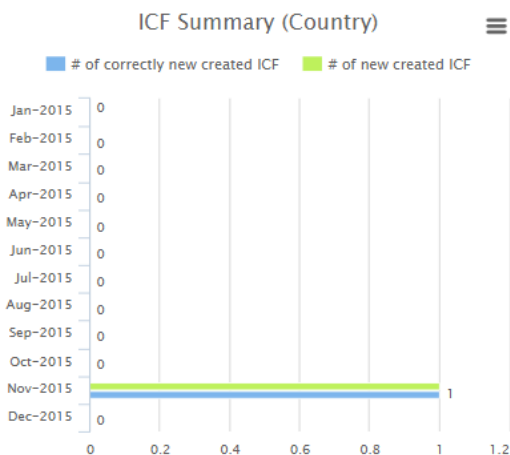
- g. CPL can modify more than one records through downloaded excel file, after update records in excel, click "IMPORT" button, choose excel file, click "upload", click "ok".



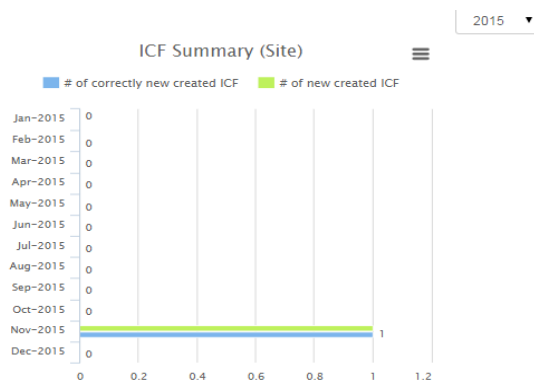
## 4.10 ICF

Display "ICF Summary(Country)", "ICF Summary(Site)", and maintain ICF records.

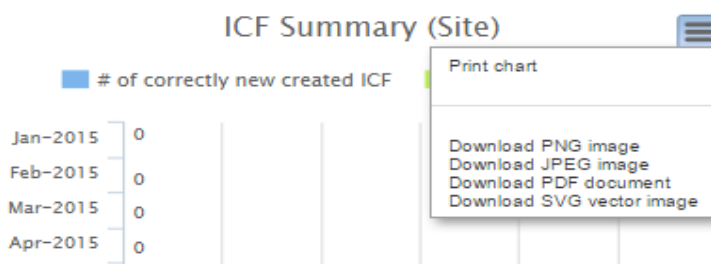
- a. Display "ICF Summary(Country)"



- b. Display "ICF Summary(Site)"



- c. Click "Print Picture" button to test download chart as different format

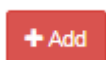


- d. Use filter area to filter sites.

--Select Site--

- 262200-Liaoning cancer Hospital & Institute
- 262202-The 1st Affiliated Hospital of Nanchang University
- 262274-The First Affiliated Hospital of Zhengzhou University
- 262275-The Fourth Hospital of Hebei Medical University (Hebei Cancer Hospital)
- 262276-Liaoning cancer Hospital & Institute
- 262278-307 Hospital of The Chinese PLA; The First Medical Dept of

- e. Click on "Add" or "Edit" button to add or edit a record



	Country/Site	Site #	Site Name	Site Status	Ver.	Ver. Date	Doc. Rev. & Appr. Form
Edit	Site	262197	West China Hospital,...	Active	1	2015-11-16	Ok

- f. Click on dropdown button for "Country/Site", and select either Country or Site; Click on dropdown button for "Doc. Rev. & Appr. Form", select OK/No.; Input information in "Version" & "Version Date" fields.

	Country/Site	Site #	Site Name	Site Status	Ver.	Ver. Date	Doc. Rev. & Appr. Form
	Site	262197-262197	West China Hospital,...	Active	1	2015-11-16	--gcp_for00422--
	NA	NA	NA-NA	NA-NA	1	2015-11-16	Ok

- g. Click "Save" to save record.

- h. Click "Export" to export ICF data, and generate excel file.



- i. Open excel file to view data.

Country/Site	Site #	Account Name	Site Status	Version	Version Date	Review and Approval Form (gcp_for004222)
Site	262197	West China Hospital, Sichuan University	Active	1	2015/11/16	Ok

## 4.11 Recruitment

### 4.11.1 Country Recruitment

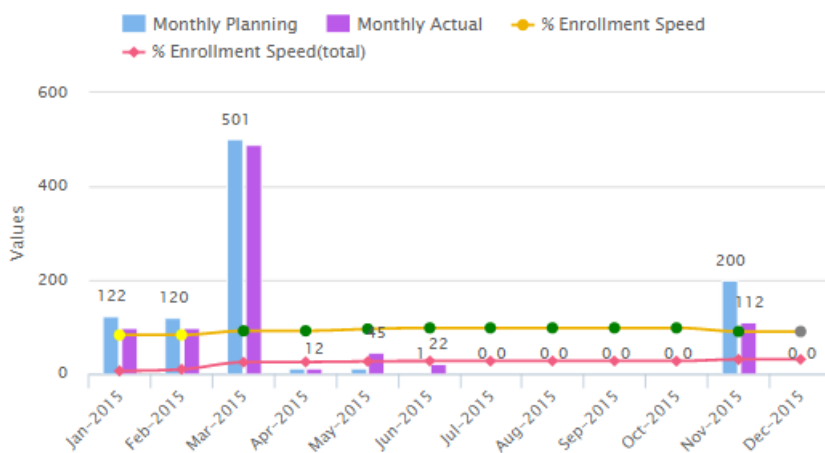
Display "Country Level Enrollment Progress" for current study, and maintain recruitment record.

- a. Display "Country Level Enrollment Progress"

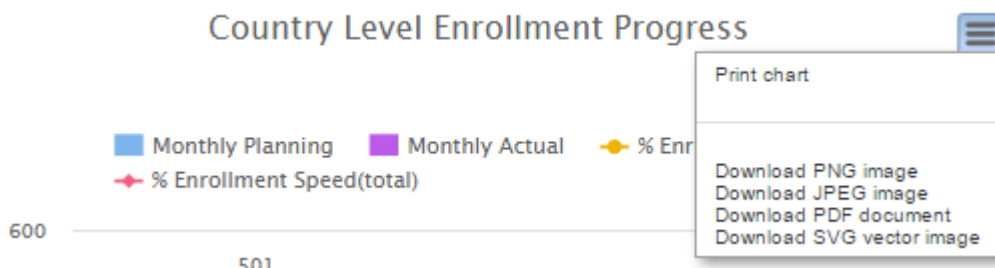
Formula: Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100%

Enrollment Speed(till the reporting month) , (total) % of Enrollment = cumulative actual/planned # enrolled (total target)\*100%

Country Level Enrollment Progress



- b. Click "Print Picture" button to download chart as different format.



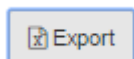
- c. Display Revised Planned # Enrolled, First Subject Enrolled (FPI), Last Subject Enrolled (FPI), Calculated Planned # Enrolled

Revised Planned # Enrolled	3204	First Subject Enrolled (FPI)	2013-04-25
Calculated Planned # Enrolled	1289	Last Subject Enrolled (FPI)	2017-06-30

- d. Maintain monthly recruitment record, and clicks save to save record.

Date	Monthly Planning	Monthly Actual
Jan-2015	122	100
Feb-2015	120	100
Mar-2015	501	490
Apr-2015	12	12
May-2015	12	45
Jun-2015	1	22
Jul-2015	0	0
Aug-2015	0	0
Sep-2015	0	0
Oct-2015	0	0
Nov-2015	200	112

- e. Click "Export" to export Country Recruitment data, and generate excel file



- f. Open excel file to view data

Country\_Recruitment.xls - Microsoft Excel

	A1						
	Date	Monthly Planning	Monthly Actual	Enrollment Speed			
1	Dec-14	120	100	0.83			
2	Jan-15	122	100	0.82			
3	Feb-15	120	100	0.83			
4	Mar-15	501	490	0.98			
5	Apr-15	12	12	1			
6	May-15	12	45	3.75			
7	Jun-15	1	22	22			
8	Jul-15	0	0 NaN				
9	Aug-15	0	0 NaN				



### 4.11.2 Site Recruitment

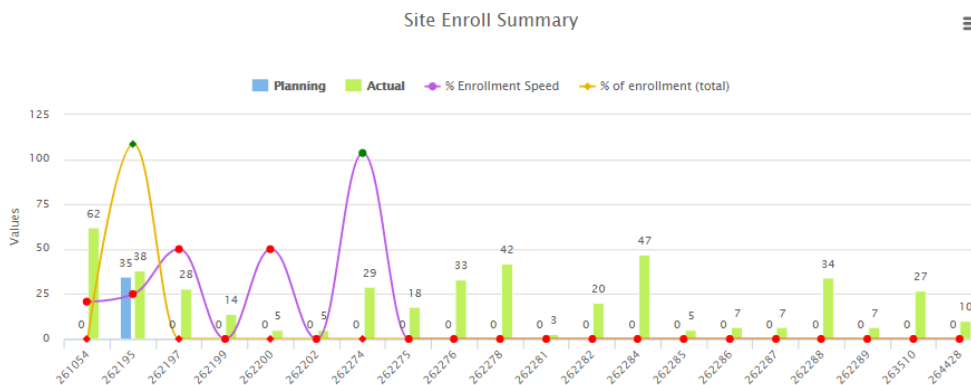
Display "Site Enroll Summary", maintain site recruitment record

a. Display "Site Enroll Summary"

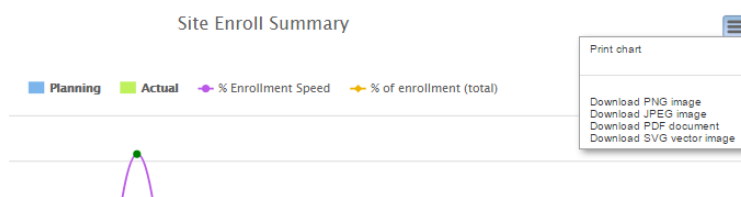
Formula:

Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100%

Enrollment Speed (till the reporting month) , (total) % of Enrollment = cumulative actual/planned # enrolled (total target)\*100%



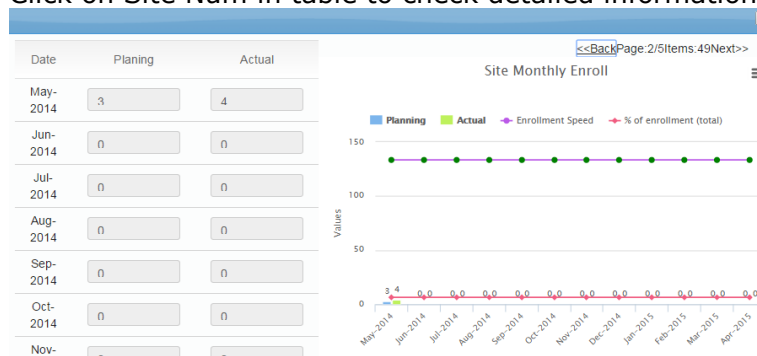
b. Click "Print Picture" button to download chart as different format



c. In the site recruitment table, manually input "planning", "actual", and click save to save record.

Site Num	Site Name	Site Status	Lastest Month			Revised Enrolled	Actual # Enrolled	Enroll Speed	Total Speed	FPI
<a href="#">261054</a>	BEIJING CANCER H...	Active	Nov-2015:Planing	<input type="text" value="2"/>	Actual <input type="text" value="2"/>	0	62	20.77%	0%	201042

d. Click on Site Num in table to check detailed information.



e. Click "Export" to export Site Recruitment data, and generate excel file.



f. Open excel file to view data.

	Actual #	Enrolled	Enroll Speed	% of enrollment (total)	FPI	LPI	DateLabel	Planning	Actual	MonthlyDetail	Enroll Speed	% of enro
1							May-13	0	0		0	
2							Jun-13	0	0		0	
3							Jul-13	0	0		0	
4							Aug-13	0	0		0	
5							Sep-13	0	0		0	
6							Oct-13	0	0		0	
7							Nov-13	0	0		0	
8							Dec-13	0	0		0	
9							Jan-14	0	0		0	
10							Feb-14	0	0		0	
11							Mar-14	0	0		0	
12							Apr-14	0	0		0	
13							May-14	3	4		133.33	
14							Jun-14	0	0		133.33	

## 5. Operation: LM

LM (Line Manager) can only view all China studies information, and detailed study information, but do not have permission to maintain study details.

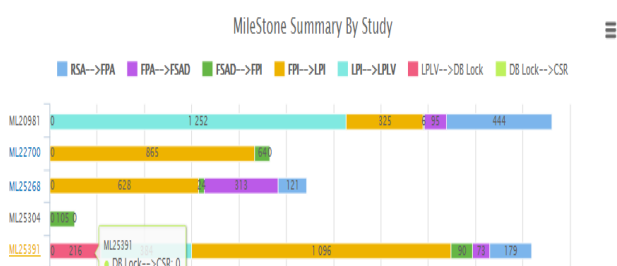
### 5.1 Access Home Page

On Home Page, Line Manager can see all on-going studies of China.

<http://spdwweb01.shp.roche.com/sites/StudyPortal/SitePages/HomePage.aspx>

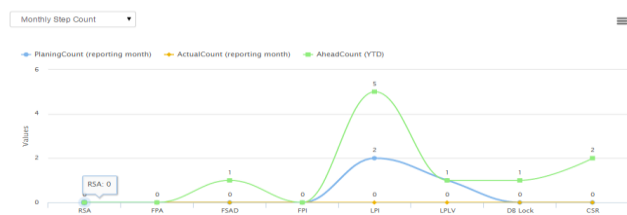
#### 5.1.1 Milestone Summary by Study

Display duration between two consecutive Milestones

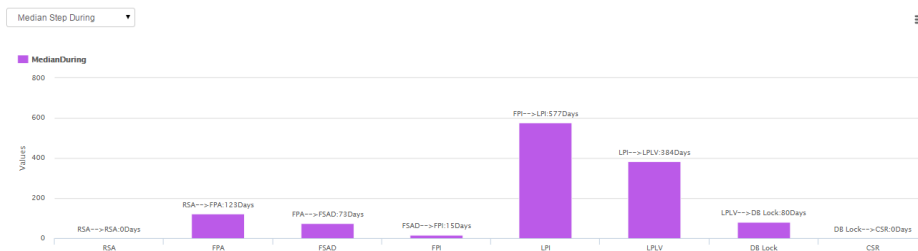


#### 5.1.2 Monthly Step Count/ Median Step During

a. Planning count (Reporting Month), Actual count (Reporting Month), Ahead count(YTD) is counts of Actual date < Planned date at each milestone level.

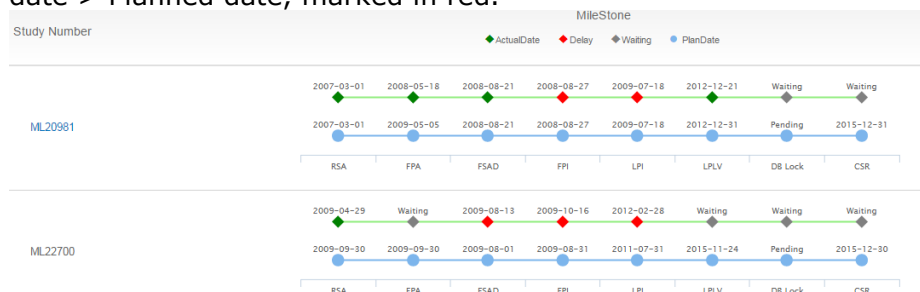


- b. Click on arrow to view Median Step During, which means the median duration days between two consecutive milestones.



### 5.1.3 Study Milestone details

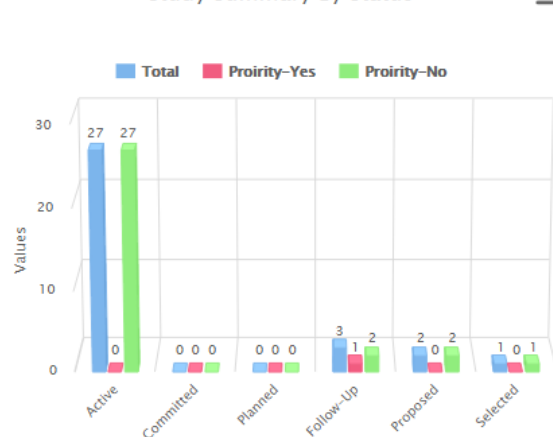
Display Study Milestone details, If Actual date  $\leq$  Planned date, marked in green, If Actual date  $>$  Planned date, marked in red.



### 5.1.4 Study Summary by Status

Display counts of Study by different status and priority.

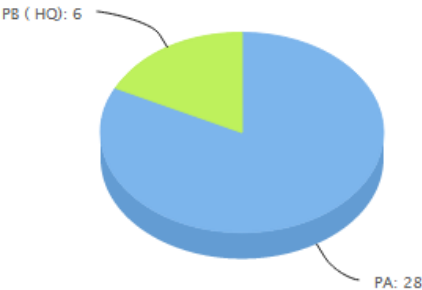
Study Summary By Status



### 5.1.5 Study Summary by GPS

Display counts of Study by GPS.

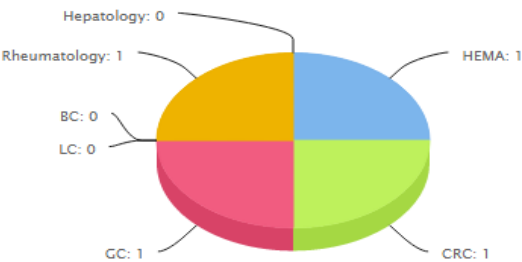
Study Summary By GPS



5.1.6 Study Summary by DA

Display counts of Study by DA.

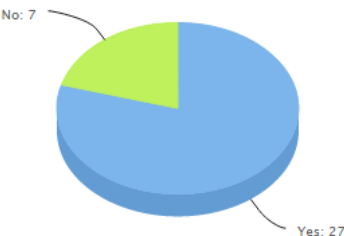
Study Summary By DA



5.1.7 Study Summary by Interventional

Display counts of Study by Interventional.

Study Summary By Interventional



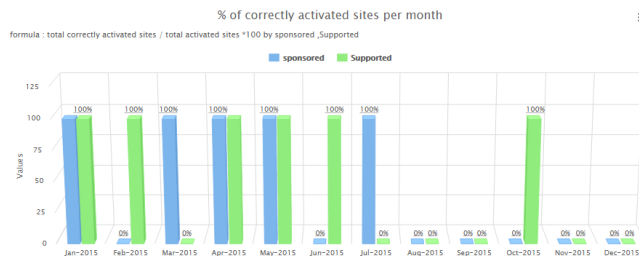
### 5.1.8 Site Activation

Display % of correctly activated sites per month.

Formula: Corrected active sites/total activated sites

Site Activation

2015



### 5.1.9 Recruitment

Display Enrollment Speed by Study

Formula:

% enrollment speed: Cumulative Actual/Cumulative Planning

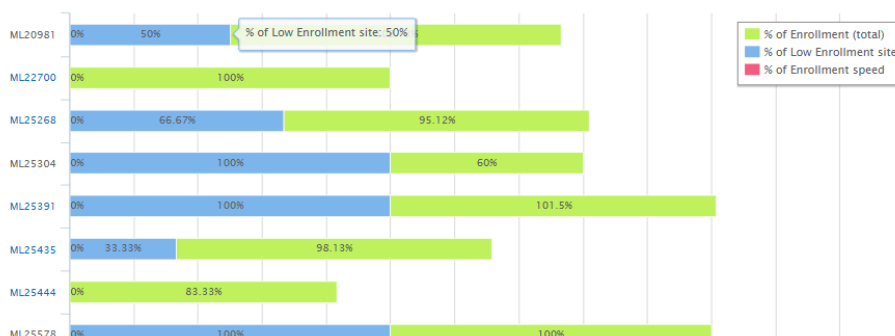
% enrollment (total): SCNTR\_ACTUALNUMENROLLED/PLANNEDNUMENROLLED

% low enrollment site: Low percent counts of site /Total counts

Recruitment

Enrollment Speed by Study

formula: %Enrollment Speed (total) = cumulative actual / planned total target \* 100, % Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100, % of low enrollment site = number of low enrollment site / total selected sites \* 100, low enrollment site is site with enrollment speed <=80%



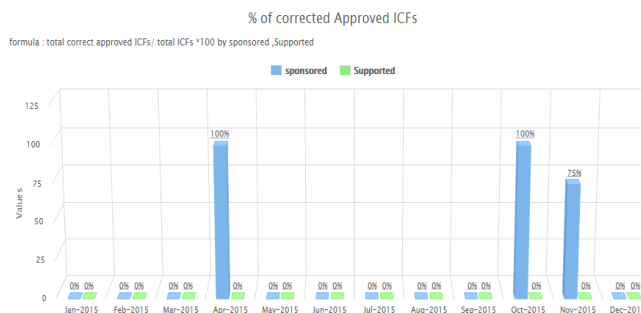
#### 5.1.10 ICF

Display % of correctly approved ICFs

Formula: Correctly approved ICFs/total ICFs

ICF

2015



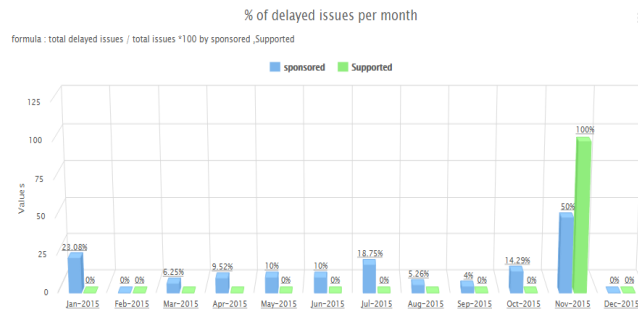
### 5.1.11 Issue Log

Display % of delayed issues per month

Formula: Delayed issues/Total issues

[Issue Log](#)

2015



### 5.1.12 Trial Monitor

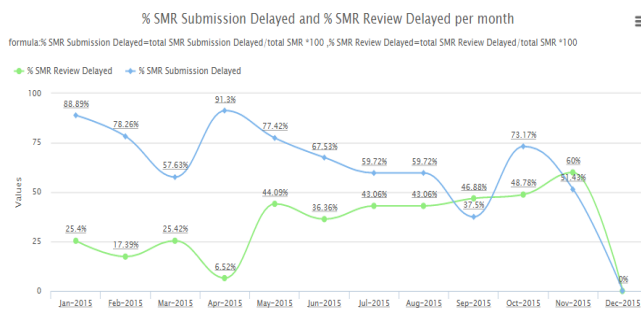
Display % SMR submission delayed and % SMR review delayed per month

Formula:  $SMRReviewDelay = DelaySToRCount / TotalCount$

$SMRSubmissiondelay = DelayCToSCount / TotalCount$

[Trial Monitor](#)

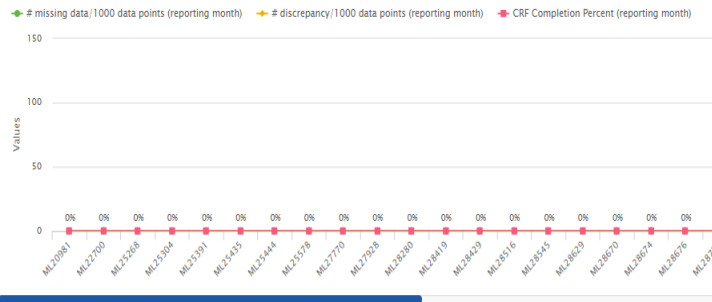
2015



### 5.1.13 CRF

Display # missing data/1000(reporting month), # discrepancy data/1000(reporting month), CRF completion %

CRF



### 5.1.14 Safety Reference

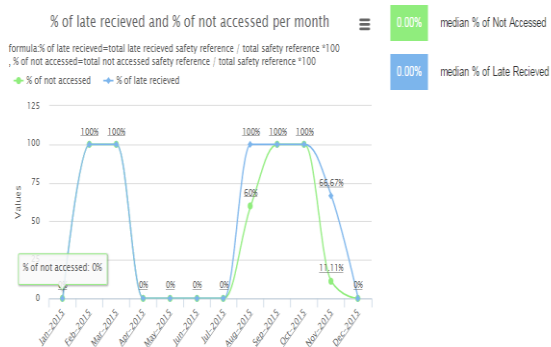
Display % of late received and % of not accessed per month

Formula: 1) % of "Not Accessed" for each site = number of "not accessed" / number of all documents (removed document is excluded).

2) % of late received for each site = number of late received document / number of all documents, late received means the time between the "date document was first accessed by the site" and "document upload date" is larger than 14 calendar days.

Safety Reference

2015



## 5.2 Overview Page

Overview page display single detailed study information, Line Manager can check /uncheck filter to display relevant information.

Overview of Study

☐ ALL ☒ General Information ☒ Country Timeline ☒ Site Timeline Median Duaring ☐ Site Activation ☐ CRF ☐ ICF ☐ Safety Reference ☐ Issue Log ☐ Recruitment ☐ Trial Monitor

## 5.2.1 General information

Display General Information for current study.

### General Information

Study No.	ML25304	Country Status	Active	Revised Planned # Site	17
Product	Cisplatin,Tarceva,Vials containing powder for solution for infusion.	Executing Party	Investigator	Actual # Site	14
DA *	Rheumatology	Accountable Roche Party	PA	Revised Planned # Enrolled	90
Interventional Study	Yes	Priority *	No	Actual # Enrolled	54
Study Short Title	Neoadjuvant T vs GC in IIIA-N2 NSCLC with EGFR(+)				
Comment					
<a href="#">SAVE</a>					

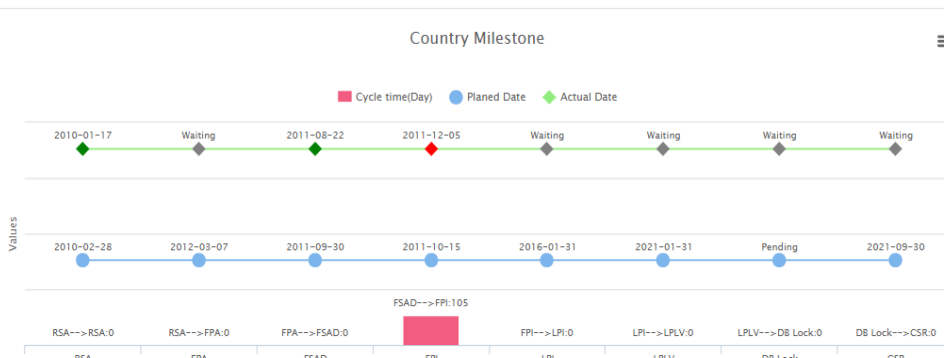
## 5.2.2 Country Timeline

Display current study of Country Milestone

Formula:

Cycle Time=duration days between two consecutive milestones, If actual date > planned date, highlight the milestone with red.

### Country Timeline



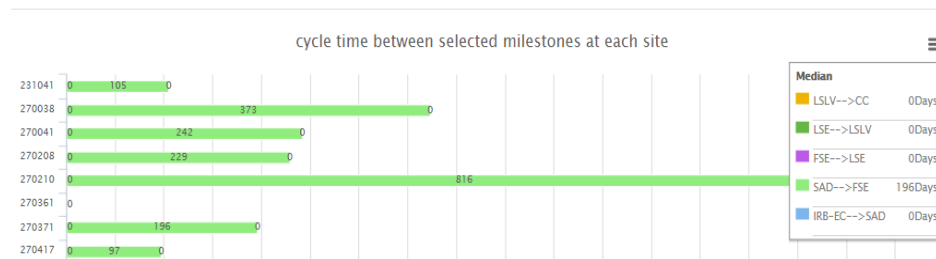
## 5.2.3 Site Timeline Median Duration

Display current study of Cycle time between selected milestones at each site.

Formula:

Duration days between two consecutive milestones

### Site Timeline Median Duration





## 5.2.4 Recruitment

Display current study of Country level enrollment Progress

Formula:

% of enrollment (total) = cumulative actual / planned total target \* 100

Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100

% of low enrollment site = number of low enrollment site / total selected sites \* 100

low enrollment site is site with enrollment speed <=80%

### Recruitment

% of enrollment (total) = cumulative actual /  
planned total target \* 100%

30.62%

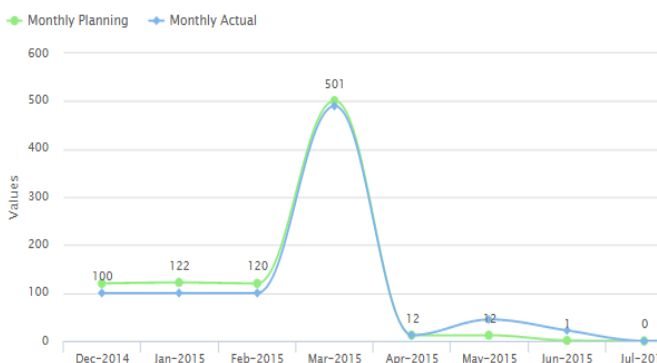
Enrollment Speed (till the reporting month) =  
cumulative actual / cumulative planning \* 100

90.17%

% of low enrollment site = number of low  
enrollment site / total selected sites \* 100%,  
low enrollment site is site with enrollment  
speed <=80%

100%

### Country Level Enrollment Progress

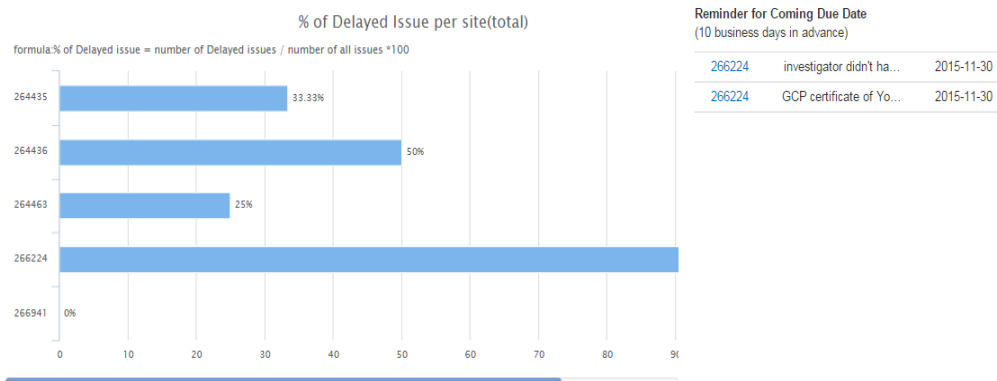


## 5.2.5 Issue log

Display current study of % of delayed issues per site (total), and the "Reminder for Coming Due Date" displayed on the right.

Formula: 10 Business days reminder for coming due date

### Issue Log



## 5.2.6 Trial Monitoring

Display current study of SMR review delayed and % SMR submission delay per month

Formula:

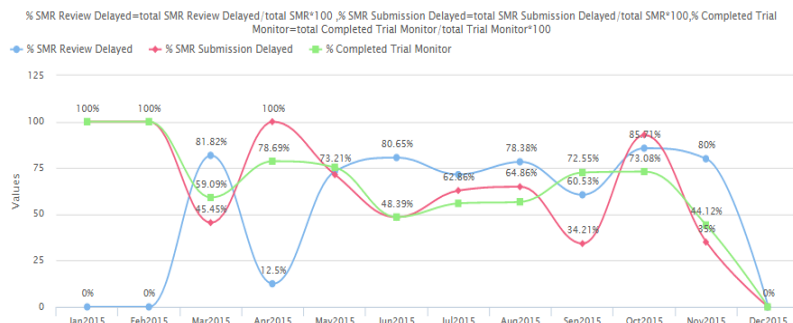
% of SMR Submission Delay in the reporting month (Date Submitted falls in the reporting month) = number of "Comp. - Sub." >5 / number of submitted SMR \* 100

% of SMR Review Delay in the reporting month (Date Reviewed falls in the reporting month) =  
number of "Sub. - Rev." >5 / number of reviewed SMR \* 100

Trial Monitor

2015

% SMR Review Delayed and % SMR Submission Delay per Month



## 5.2.7 Safety Reference

Display current study of % of not accessed and % of late received by site

Formula:

1) % of "Not Accessed" for each site = number of "not accessed" / number of all documents (removed document is excluded).

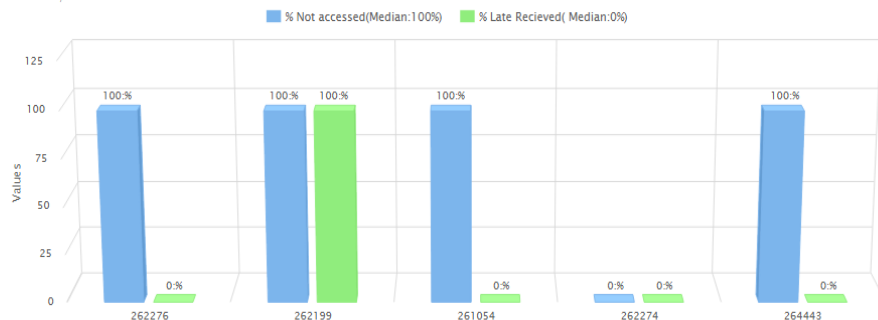
2) % of late received for each site = number of late received document / number of all documents, late received means the time between the "date document was first accessed by the site" and "document upload date" is larger than 14 calendar days.

Note: Doc. Rec by Site-Doc. Sub. Date>14

Safety Reference

% of Not accessed and % of Late Received by Site

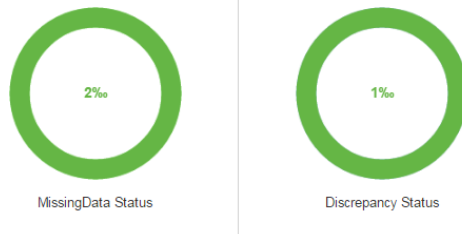
formula: % of Not Accessed for each site = number of not accessed / number of all documents, % of late received for each site = number of late received document / number of all documents



## 5.2.8 CRF

Display current study of Missing Data status and Discrepancy status

CRF



## 5.2.9 Site Activation

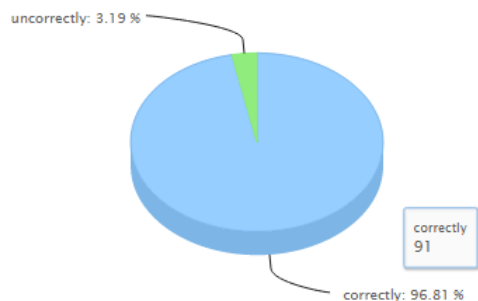
Display % of correctly activated sites for current study

Formula: % of correctly activated sites = number of correctly activated site / number of total activated site \* 100, correctly activated site is site activated with the completion of "site selection checklist" and " green light approval for site activation"

[Site Activation](#)

% correctly activated

% of correctly activated sites = number of correctly activated site / number of total activated site \* 100%




## 5.2.10 ICF

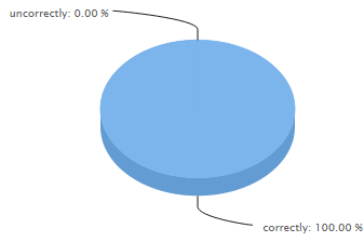
Display % correctly approved sites for current study

Formula: % of ICFs which correctly approved for each month, ICF which correctly approved means the "gcp\_for004222" is OK status.

## ICF

% correctly approved(reporting month) 

% of ICFs correctly approved = number of correctly % of correctly approved ICFs/number of ICFs \* 100%



## 5.3 Time Line

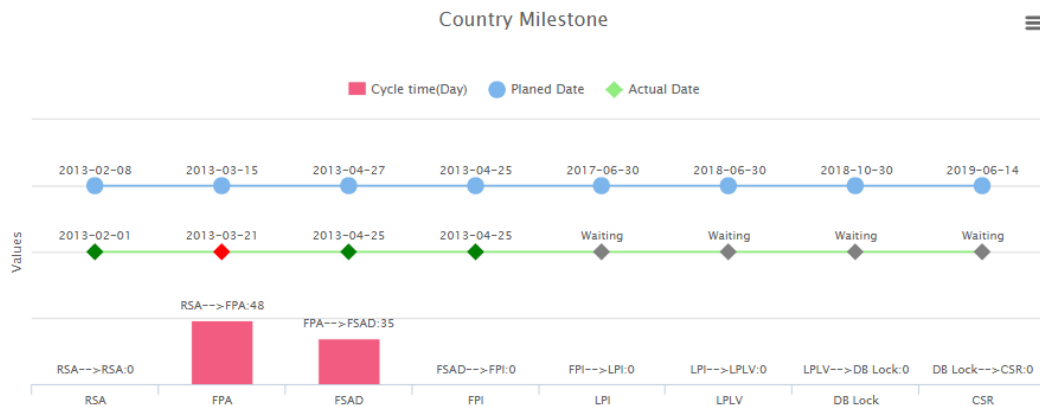
### 5.3.1 Country Time Line

Display Country milestone, duration days between two consecutive milestones,  
Setting: if actual date > planned date, highlight the milestone with red

#### Country Timeline

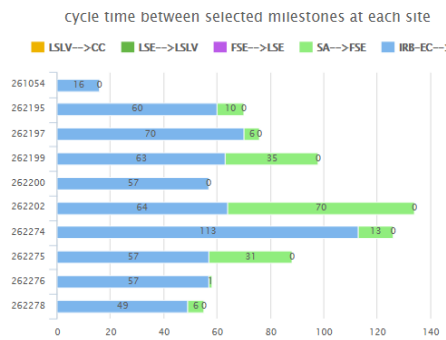
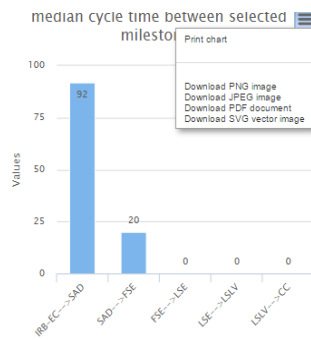
Key milestones at country and site level are captured here (all data from CTMS, no manual entry is required).

Metric: Cycle time (measured in days) between two consecutive milestones. Long cycle times could indicate that the site should try to identify areas where the process is delayed. The point's color of delay milestone will be marked with 'red'



### 5.3.2 Site Time Line

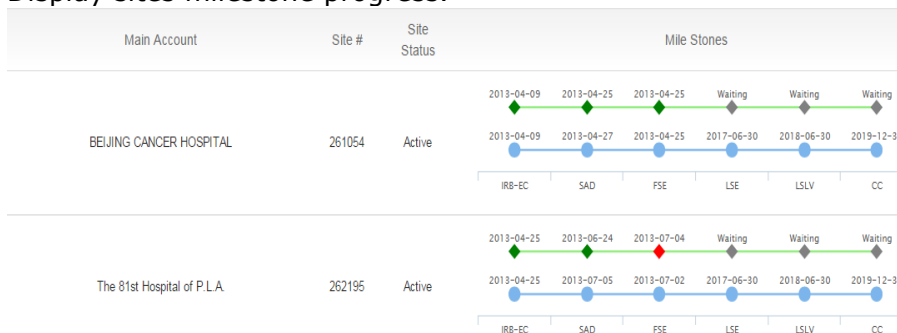
- Display "Median cycle time between selected milestones"
- Display "Cycle time between selected milestones at each site"
- Click "Print Picture" button to download chart as different format



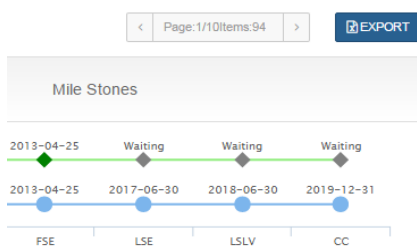
d. Locate filter area to select or search sites.

261054-BEIJING CANCER HOSPITAL  
262195-The 81st Hospital of P.L.A.  
262197-West China Hospital, Sichuan University  
262199-Changzhou First People's Hospital  
262200-Liaoning cancer Hospital & Institute  
262202-The 1st Affiliated Hospital of Nanchang University  
262274-The First Affiliated Hospital of Zhengzhou University  
262275-The First Hospital of Hubei Medical University (Hubei Cancer Hospital)

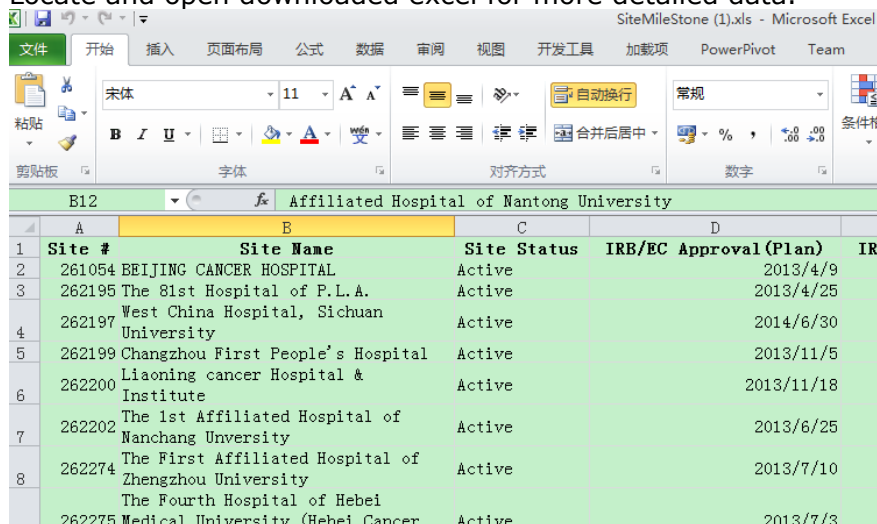
e. Display sites milestone progress.



f. Click "Export" to export Time Line, and generate excel file



- g. Locate and open downloaded excel for more detailed data.








The screenshot shows an Excel spreadsheet titled 'SiteMilestone (1).xls'. The table has columns: Site #, Site Name, Site Status, IRB/EC Approval (Plan), and IRB/EC Approval Date. The data is as follows:

Site #	Site Name	Site Status	IRB/EC Approval (Plan)	IRB/EC Approval Date
261054	BEIJING CANCER HOSPITAL	Active		2013/4/9
262195	The 81st Hospital of P.L.A.	Active		2013/4/25
262197	West China Hospital, Sichuan University	Active		2014/6/30
262199	Changzhou First People's Hospital	Active		2013/11/5
262200	Liaoning cancer Hospital & Institute	Active		2013/11/18
262202	The 1st Affiliated Hospital of Nanchang University	Active		2013/6/25
262274	The First Affiliated Hospital of Zhengzhou University	Active		2013/7/10
262275	The Fourth Hospital of Hebei Medical University (Hebei Cancer	Active		2013/7/3

## 5.4 SMT Chart



- a. View SMT Chart in detailed.

Image	IsOwner	Domain Name	Name	Role	Roche/Sponsor/CRO	Company Name	Start Date	End Date	Comment
 Edit			tyy	Data Manager	Roche	ddd	2015-10-01		
 Edit		RMOASIA/GUT2	333	CPL	Roche	33	2015-10-31		2321
 Edit	Yes	RMOASIA/HEY24	yongjian.tang	CPL	Sponsor	1212	2015-10-06		1212
 Edit			trtrt	MSL	CRO	44	2015-10-30	2015-11-11	65
 Edit			ttt	Project Manager	CRO	9u8u8	2015-10-01	2024-10-16	999

- b. Click "Arrow" button on filter area to filter Status/Roles/Company type.

--Status-- --Roles-- --CompanyType--

- c. If "End" Date is blank, the image highlight as "blue", if "End" Date is added, the image highlight as "grey".

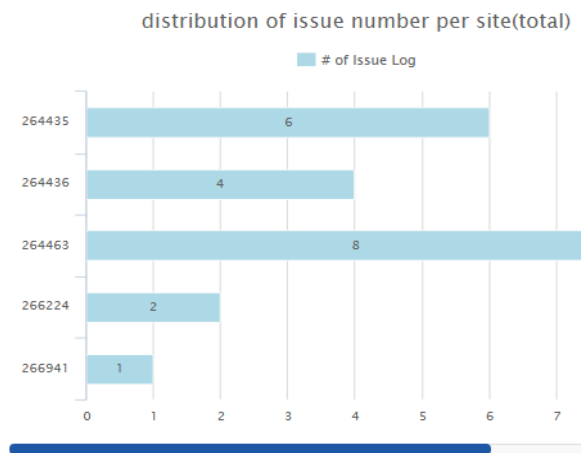
Image	IsOwner	Domain Name	Name	Role	Roche/Sponsor/CRO	Company Name	Start Date	End Date	Comment
 Edit			tyy	Data Manager	Roche	ddd	2015-10-01		
 Edit		RMOASIA/GUT2	333	CPL	Roche	33	2015-10-31		2321

**Note:** IsOwner means backup team member who is also in charge of current study as backup role, by default, the value is "No". If CPL assigned a backup member, the value is "Yes", and the "Domain Name" is Roche User ID (ex, GUT2)

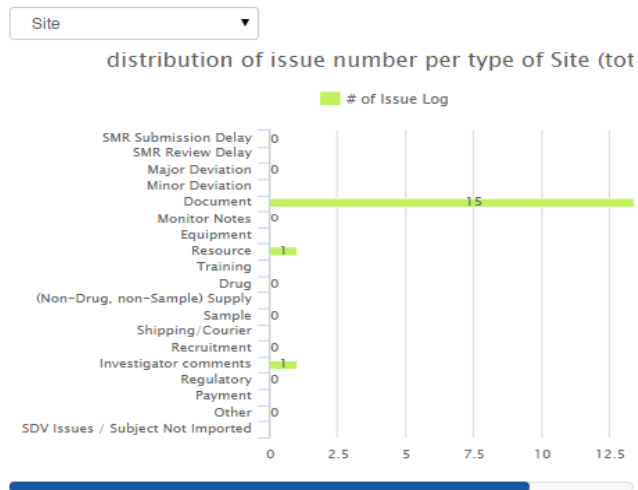
- d. Click "Export" to export team members, and generate excel file.

## 5.5 Issue Log

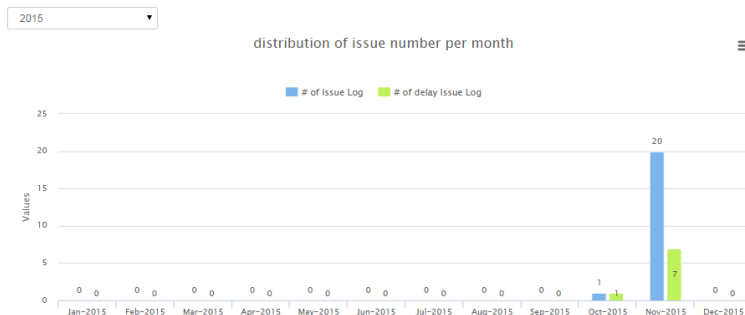
### a. Display "Distribution of issue number per site(total)"



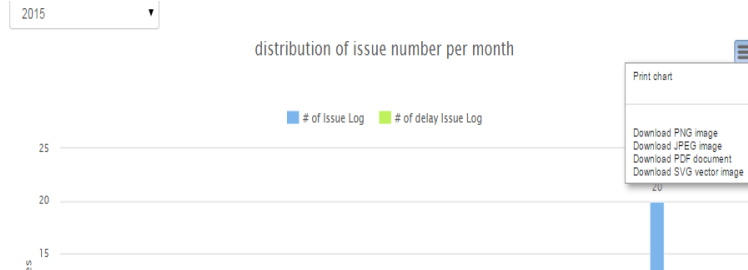
### b. Display "Distribution of issue number per type of site(total)"



### c. Display "Monthly issue log summary"



- d. Click "Print Picture" button to download chart as different format



- e. Check issue log records table for more details.

1/100

low Num: 10 --Subject: --Issue: Page: 1/3 Items: 21 + ADD EXPORT

Site #	Account Name	Site Status	Site or Subject	Issue Type	Description	Planned Action	Resolution
264435	Fujian Medical Unive...	Active	Site	Document	The newsletters, wer...	SM to print the newsl...	CRA filed in
264435	Fujian Medical Unive...	Active	Site	Document	2014 local lab certfic...	CRA will collect from ...	SN collected th
264435	Fujian Medical Unive...	Active	Site	SDV Issues/Subject N...	ICF process of subje...	CRA to confirm with i...	CRA communic
264435	Fujian Medical Unive...	Active	Site	Document	Qiuping Huang's dele...	CRA to confirm with ...	PI ended the d
264435	Fujian Medical Unive...	Active	Site	SDV Issues/Subject N...	ICF process of Subje...	CRA to confirm with i...	CRA confirmed
264435	Fujian Medical Unive...	Active	Site	Document	All of the SI's GCP c...	CRA will collect SI d...	CRA collected f

Site # 264435-Fujian Medical University Union Hospital Site Name Fujian Medical University Union Hospital

Site Status Active Site or Subject Site

Issue Type Document Issue Status Closed

Observation Date 2015-10-14

Due Date 2015-11-11 Completed Date 2015-11-11

Description The newsletters, weren't filed in ISF.

Planned Action SM to print the newsletter and send to CRA, CRA to file in ISF during this visit.

Resolution CRA filed in ISF

OK

- f. Rule Setting in table
- Reminder: 10 business days before Due Date, highlight "Due Date" with yellow
- Delay: completed date > due date, highlight the "Completed date" with red



Due Date	Comp. Date
2015-11-27	
2015-11-20	
2015-11-13	
2015-11-20	
2015-11-30	
2015-11-30	

- g. Click "Export" to export Issue Log data as excel file



- e. Open excel file to view detailed data

Site #	Account Name	Site Status	Site or Subject	Issue Type
264435	Fujian Medical University Union Hospital	Active	Site	Document
264435	Fujian Medical University Union Hospital	Active	Site	Document
264435	Fujian Medical University Union Hospital	Active	Site	SDV Issues/Subject Not Imported

## 5.6 Case Report Form

- a. View CRF chart in detailed

Date	% discrepancy	% missing data	% Completion	Comments	Discrepancy Status	MissingData Status	Completion Status
Dec-2015	30	10	1		30%	10%	1%

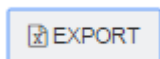
Note:

if # of discrepancy/1000 data points >100, highlight with red

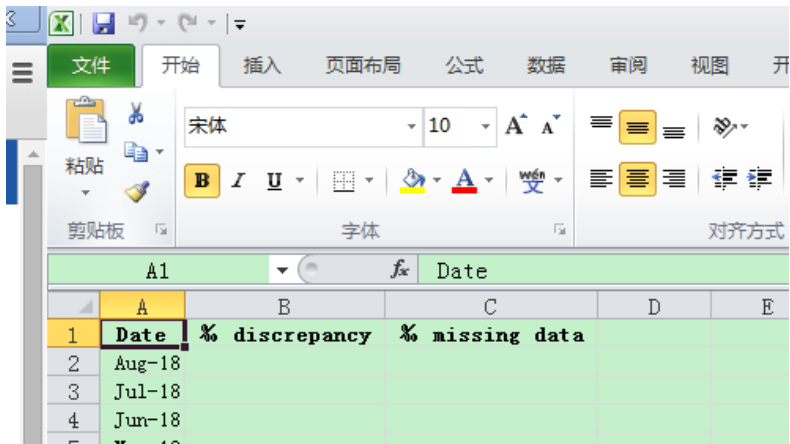
if # of missing data/1000 data points >200, highlight with red; if >=100 and =<200, amber

CRF completion percent <= 80%, highlight with red

- b. Click "Export" to export Case Report Form data as excel file



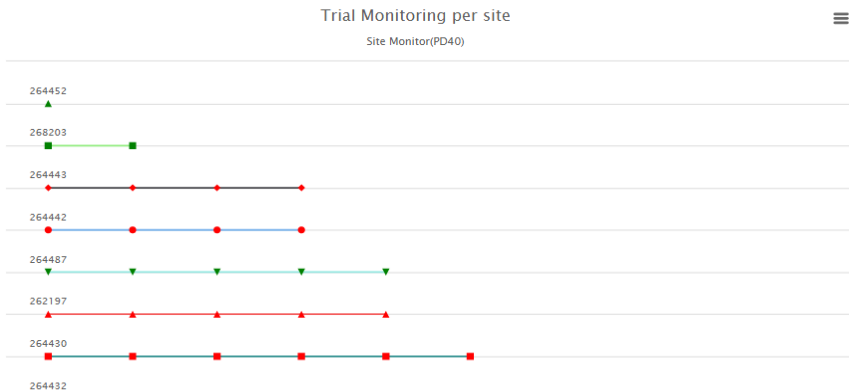
c. Open excel file to check CRF data.



	A	B	C	D	E
1	Date	% discrepancy	% missing data		
2	Aug-18				
3	Jul-18				
4	Jun-18				
5	May-18				

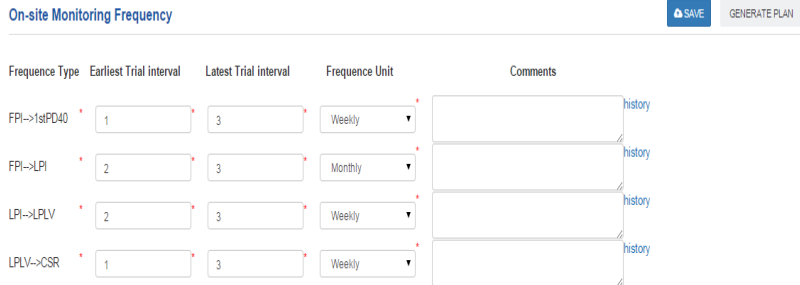
## 5.7 Trial Monitoring

a. View Trial Monitoring per site.



Formula: Green in chart: Activity Start Date of PD40 in the range of Earliest Trial Date and Latest Trial Date  
Red in chart: Activity Start Date of PD40 out the range of Earliest Trial Date and Latest Trial Date

b. View "On-site Monitoring Frequency"



On-site Monitoring Frequency

SAVE GENERATE PLAN

Frequency Type	Earliest Trial Interval	Latest Trial Interval	Frequency Unit	Comments
FPI->1stPD40	1	3	Weekly	history
FPI->LPI	2	3	Monthly	history
LPI->LPLV	2	3	Weekly	history
LPLV->CSR	1	3	Weekly	history

c. View Trial Monitoring details.

Site #	Account Name	Site Status	Act. Type	Comm. Type	Earliest Trial	Latest Trial	ASD	ACD
261054	BEIJING CANCER H...	Active	Site Pre-Activation (PD30)				2013-04-25	2013-04-25
261054	BEIJING CANCER H...	Active	Site Monitoring (PD40)		2013-05-02	2013-05-16	2015-01-28	2015-01-28
261054	BEIJING CANCER H...	Active	Site Monitoring (PD40)		2013-07-16	2013-08-16	2015-04-10	
261054	BEIJING CANCER H...	Active	Site Monitoring (PD40)		2013-10-16	2013-11-16	2015-05-15	2015-05-15
261054	BEIJING CANCER H...	Active	Site Monitoring (PD40)		2014-01-16	2014-02-16	2015-05-29	2015-05-29

- d. Check traffic light in data table.

Formula: if  $\text{Comp-Sub}(\text{SubmittedDate}-\text{ACD})/\text{Sub.-Rev}(\text{DateReviewed}-\text{SubmittedDate}) > 10$ , red;  $10 \geq$  and  $> 5$ , yellow.

Submitted Date	Comp. - Sub.	Report Status	Date Reviewed	Sub. - Rev.
2013-05-23	28	Reviewed	2013-05-23	0
2015-03-11	42	Reviewed	2015-03-11	0
	0	Planned		0
2015-05-22	7	Reviewed	2015-05-30	8

- e. Click "Export" to export Case Report Form data as excel file



- f. Open excel file to check data.

Site #	Site Name	Site Status	Activity Type	Communication Type
261054	BEIJING CANCER HOSPITAL	Active	Site Pre-Activation (PD30)	
261054	BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
261054	BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
261054	BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
261054	BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
261054	BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
261054	BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	
261054	BEIJING CANCER HOSPITAL	Active	Site Monitoring (PD40)	

## 5.8 Site Activation

- a. View Site Activation details.

## Site Activation

Does site activation meet all requirements? Are "site selection checklist" and "green light approval for site activation" ready?

Metric: % of correctly activated sites = number of correctly activated site / number of total activated site \* 100%, correctly activated site is site activated with the completion of "site selection checklist" and "green light approval for site activation"

Sites							
<div> <div>&lt; Page: 1/8 Items: 94 &gt;</div> <div>EXPORT</div> <div>SAVE</div> </div>							
Site Name	Site #	Site Status	SSC	IRB/EC	SCA	GLA	SAD
BEIJING CANCER H...	261054	Active	No	2013-04-09	2013-04-19	Yes	2013-04-25
The 81st Hospital of ...	262195	Active	No	2013-04-25	2013-04-25		2013-06-24
West China Hospital, ...	262197	Active	No	2014-07-02	2014-09-05	No	2014-09-10
Changzhou First Peo...	262199	Active		2013-11-05	2013-12-31		2014-01-07
Liaoning cancer Hos...	262200	Active		2013-11-18	2013-12-31		2014-01-14
The 1st Affiliated H...	262202	Active		2013-06-25	2013-08-08		2013-08-28
The First Affiliated H...	262274	Active		2013-07-10	2013-10-18		2013-10-31
The Fourth Hospital ...	262275	Active		2013-07-03	2013-08-19		2013-08-29

Note:

Setting: If ("Site Selection Checklist"="No" and "IRB/EC approval" is not blank/-), alert "Site Selection Checklist (SSC)" is red.

If ("Green Light Approval"="No" and "site activation date" is not blank/-), alert "Green Light Approval (GLC)" is red.

- b. Click "Export" to export team members, and generate excel file.

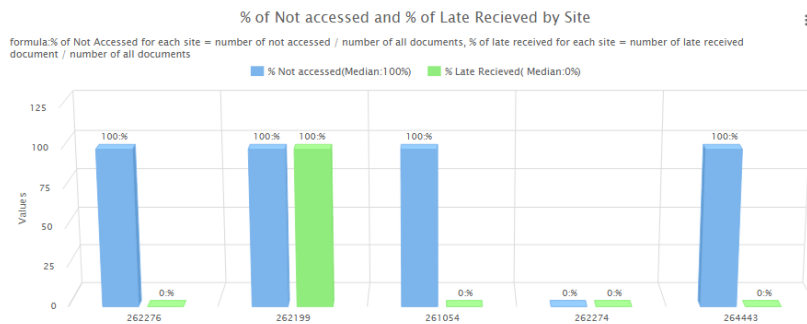


- c. Open excel file to view data.

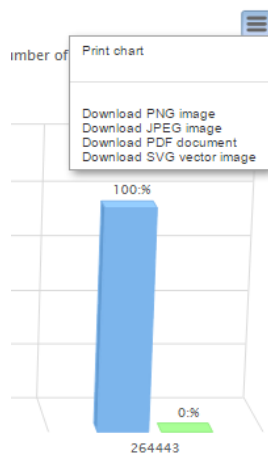
Site Activation (1).xls - Microsoft Excel							
File Home Insert Layout Formulas Data Review View Tools Add-ins PowerPivot Team							
Font Paragraph Styles							
A1 fx Site Name							
	A	B	C	D	E	F	G
1	Site Name	Site #	Site Status	SSC	IRB/EC	SCA	GLA
2	BEIJING CANCER HOSPITAL	261054	Active	No	2013/4/9	2013/4/19	2013/4/25
3	The 81st Hospital of P.L.A.	262195	Active	No	2013/4/25	2013/4/25	2013/6/24
4	West China Hospital, Sichuan University	262197	Active	No	2014/7/2	2014/9/5	2014/9/10
5	Changzhou First People's Hospital	262199	Active		2013/11/5	2013/12/31	2014/1/7
6	Liaoning cancer Hospital & Institute	262200	Active		2013/11/18	2013/12/31	2014/1/14
7	The 1st Affiliated Hospital of Nanchang University	262202	Active		2013/6/25	2013/8/8	2013/8/28
8	The First Affiliated Hospital of Zhengzhou University	262274	Active		2013/7/10	2013/10/18	2013/10/31
9	The Fourth Hospital of Hebei Medical University (Hebei Cancer Hospital)	262275	Active		2013/7/3	2013/8/19	2013/8/29
10	Liaoning cancer Hospital & Institute	262276	Active		2013/11/18	2013/12/30	2014/1/14

## 5.9 Safety Reference

- a. View "% of Not accessed and % of late received by site".



b. Click "Print Picture" button to test download chart as different format.



c. View Safety Reference table in detailed.

	Site #	Site Name	Doc. Name	Doc. Ver.	Doc. St.	Doc. Type	Doc. Rec by Site	Doc. Sub. Date
<a href="#">Edit</a>	262276	Liaoning cancer Hos...	11	1	Not Accessed	7 Day Open Label	2015-09-30	2015-09-01
<a href="#">Edit</a>	262199	Changzhou First Peo...	11	1	Not Accessed	DSUR	2015-10-14	2015-02-05
<a href="#">Edit</a>	261054	BEIJING CANCER H...	1	1	Not Accessed	CDS	2015-10-28	2015-03-24

Note: Setting: If "Document Status" = "Not Accessed", highlight with red

d. Use filter area to filter sites.

Accessed					
	Site #	Site Name	Doc. Name	Doc. Ver.	Doc. St.
Edit	262274	The First Affiliated H...	21	221	Accessed
Edit	262274	The First Affiliated H...	21	221	Accessed
Edit	262274	The First Affiliated H...	21	221	Accessed
Edit	262274	The First Affiliated H...	21	221	Accessed

e. Click "Export" to export Safety Reference data, and generate excel file

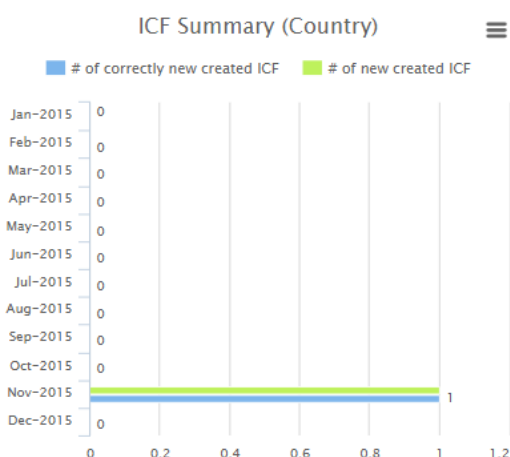


f. Open excel file to view data.

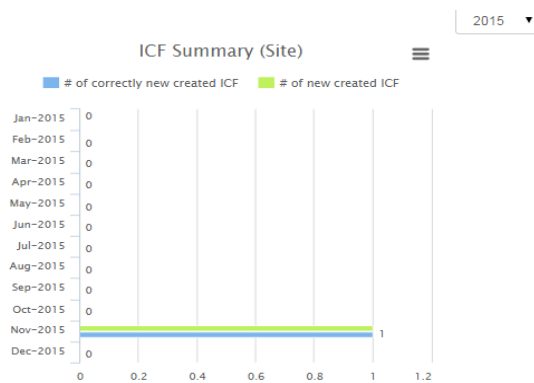
Site #	Site Name	Document Name	Document Version	Document Status	Document Type
262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	IB
262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	IB
262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	2011/3/15
262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	2011/3/15
262274	The First Affiliated Hospital of Zhengzhou University	21	221	Accessed	IB

## 5.10 ICF

a. View "ICF Summary(Country)"



b. View "ICF Summary(Site)"



- c. Click "Print Picture" button to test download chart as different format



- d. Use filter area to filter sites.

-Select Site-

262200-Liaoning cancer Hospital & Institute

262202-The 1st Affiliated Hospital of Nanchang University

262274-The First Affiliated Hospital of Zhengzhou University

262275-The Fourth Hospital of Hebei Medical University (Hebei Cancer Hospital)

262276-Liaoning cancer Hospital & Institute

262278-307 Hospital of The Chinese PLA; The First Medical Dept of


- e. View ICF table in detailed.

Site #	Account Name	Site Status	Site or Subject	Issue Type	Description	Planned Action	Resolution
264435	Fujian Medical Unive...	Active	Site	Document	The newsletters, wer...	SM to print the newsl...	CRA filed in
264435	Fujian Medical Unive...	Active	Site	Document	2014 local lab certifi...	CRA will collect from ...	SN collected th
264435	Fujian Medical Unive...	Active	Site	SDV Issues/Subjct N...	ICF process of subje...	CRA to confirm with i...	CRA communic

- f. Click "Export" to export ICF data, and generate excel file.



- g. Open excel file to view data.



Country/Site	Site #	Account Name	Site Status	Version	Version Date	SRPL-Clinical Study Document Review and Approval Form (gcp_for004222)
Site	262197	West China Hospital, Sichuan University	Active	1	2015/11/16	Ok

## 5.11 Recruitment

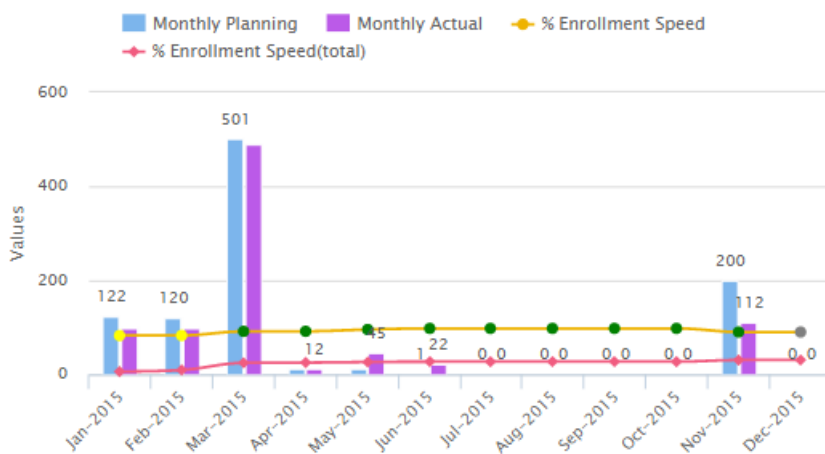
### 5.11.1 Country Recruitment

- a. View "Country Level Enrollment Progress"

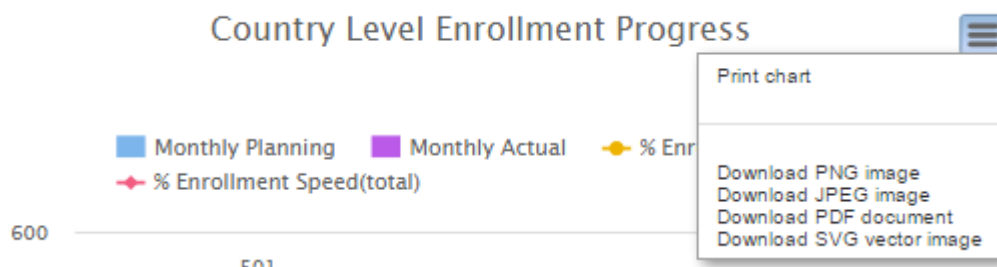
Formula: Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100%

Enrollment Speed(till the reporting month) , (total) % of Enrollment = cumulative actual/planned # enrolled (total target)\*100%

Country Level Enrollment Progress



- b. Click "Print Picture" button to download chart as different format.



- c. Display Revised Planned # Enrolled, First Subject Enrolled (FPI), Last Subject Enrolled (FPI), Calculated Planned # Enrolled

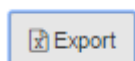


Revised Planned # Enrolled	3204	First Subject Enrolled (FPI)	2013-04-25
Calculated Planned # Enrolled	1289	Last Subject Enrolled (FPI)	2017-06-30

- d. View monthly recruitment record, and clicks save to save record.

Date	Monthly Planning	Monthly Actual
Jan-2015	122	100
Feb-2015	120	100
Mar-2015	501	490
Apr-2015	12	12
May-2015	12	45
Jun-2015	1	22
Jul-2015	0	0
Aug-2015	0	0
Sep-2015	0	0
Oct-2015	0	0

- e. Click "Export" to export Country Recruitment data, and generate excel file



- f. Open excel file to view data

Country\_Recruitment.xls - Microsoft Excel

	A	B	C	D	E	F	G
1	Date	Monthly Planning	Monthly Actual	Enrollment Speed			
2	Dec-14	120	100	0.83			
3	Jan-15	122	100	0.82			
4	Feb-15	120	100	0.83			
5	Mar-15	501	490	0.98			
6	Apr-15	12	12	1			
7	May-15	12	45	3.75			
8	Jun-15	1	22	22			
9	Jul-15	0	0 NaN				
10	Aug-15	0	0 NaN				

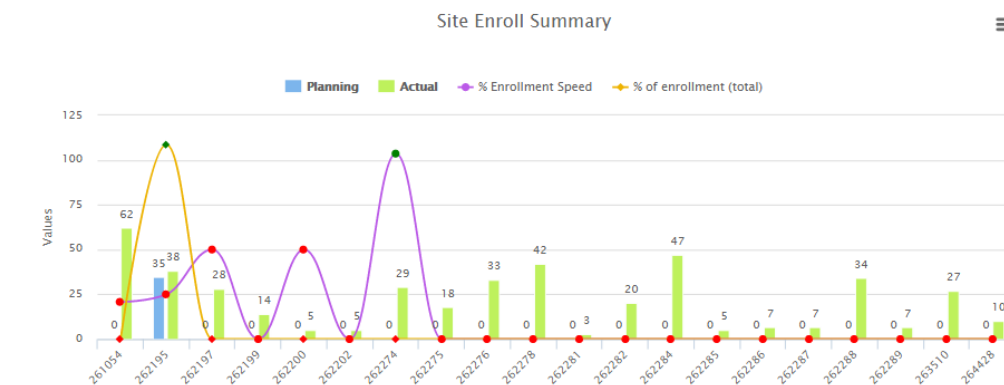
### 5.11.2 Site Recruitment

#### a. View "Site Enroll Summary"

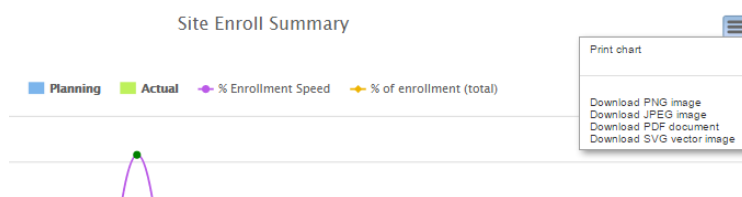
Formula:

Enrollment Speed (till the reporting month) = cumulative actual / cumulative planning \* 100%

Enrollment Speed (till the reporting month) , (total) % of Enrollment = cumulative actual/planned # enrolled (total target)\*100%



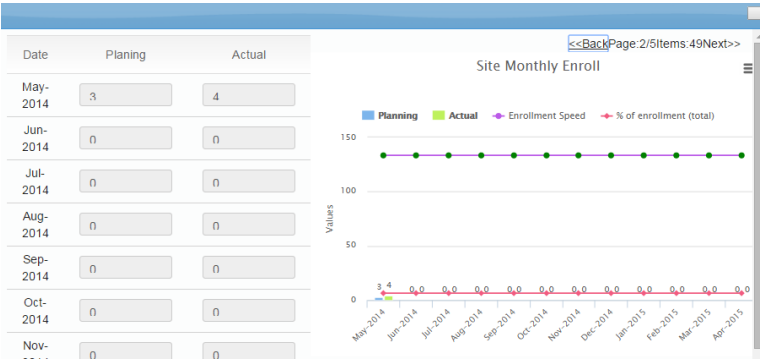
#### b. Click "Print Picture" button to download chart as different format



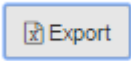
#### c. View site recruitment records in detailed

Site Num	Site Name	Site Status	Lastest Month		Revised Enrolled	Actual # Enrolled	Enroll Speed	Total Speed	FP		
<a href="#">261054</a>	BEIJING CANCER H...	Active	Nov-2015:Planing	<input type="text" value="2"/>	Actual	<input type="text" value="2"/>	0	62	20.77%	0%	201 04-2

#### d. Click on Site Num in table to check detailed information.



e. Click "Export" to export Site Recruitment data, and generate excel file.



f. Open excel file to view data.

The screenshot shows a Microsoft Excel spreadsheet titled 'SiteRecruitment.xls'. The spreadsheet contains recruitment data. The first row (row 1) has headers: 'Actual # Enrolled', 'Enroll Speed', '% of enrollment (total)', 'FPI', 'LPI', 'DateLabel', 'Planning', 'Actual', 'Enroll Speed', and '% of enro'. The subsequent rows (rows 2-16) contain data for months from May-13 to Jun-14. The 'Actual # Enrolled' column shows values 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 3, 4, 0. The 'Enroll Speed' column shows values 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 133.33, 133.33, 133.33. The '% of enrollment (total)' column shows values 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 133.33, 133.33, 133.33. The 'DateLabel' column shows months from May-13 to Jun-14. The 'Planning' column shows values 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 3, 4, 0. The 'Actual' column shows values 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 3, 4, 0. The 'Enroll Speed' column shows values 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 133.33, 133.33, 133.33. The '% of enro' column shows values 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 0, 133.33, 133.33, 133.33.