

## Project Metrics- a powerful tool that supports workload management and resource planning for Biostats & Programming department

Jian Hua (Daniel) Huang, Rajan Vohra, and Andy Chopra, BMS Corporation

### ABSTRACT

For pharmaceutical company with a large number of pipelines (i.e. several hundreds of studies ongoing) and a big group of Biostats & Programming team (i.e. > 200 people), it could be challenging for its leadership team to conduct workload management and resources planning. My team creates a “project metrics” which is aimed to collect Biostats & Programming workload related information and resource prediction. The metrics contains the key information of ‘*Biostats & Programming Deliverables*’ and they are further organized by following categories: *Function, (TA) Group, Lead, Compound, and Study*. It provides pre-defined pull-down lists (i.e. *compound list, type of deliverables list*) to ensure the consistency of data entry. In addition, it creates customized dashboard reports that give leadership team a comprehensive overview and great details. Some typical reports as listed in this paper include *number of study summary report, resources predication/gaps report, a 360-dashboard report and a Sankey Diagram of workload distribution*. Finally, some new features have been discussed and proposed as future development plan for the project metrics. As a quick summary, the project metrics provides a centralized location for data collection and a powerful tool for summary report, it increases the feasibility and efficiency for leadership team to conduct workload management and resources planning across Biostats & Programming department.

### INTRODUCTION

Managing the workload and resource planning for biostatisticians and programmers could be challenging to the leadership team due to following reason: (1) too much information to be collected (2) inconsistent way of data entry and collection (3) no powerful tool available for reporting. To address this urgent business needs, my team builds a project metrics to capture workload and resource information and provide dynamic summary report. We will introduce the ‘project metrics’ template, types of ‘dashboard report’ and ‘new feature development’ in following paragraphs in this paper.

### PROJECT METRICS

#### 1. TEMPLATE DESIGN

The overall purpose of creating this project metrics is to capture Biostats & Programming workload related information and corresponding resources predication. There are three sections of information collected per project metrics template design;

Section 1, Workload Related Information:

The first section contains workload related information. This section includes key variable called “deliverables”, such as “SAP creation” as one of statistician deliverable. In addition, what ‘type of outputs’ created by this deliverable, ‘number of outputs’ and ‘target completion date’ are also captured as important quantitative information to measure the workload. All information is organized under the categories of “*Function, (TA) Group, Lead, Compound and Study*” (see below table 1).

**Error! Reference source not found.** Project Metrics Template Design: Section 1 – Workload Related Information.

Function	Group	Lead	Compound	Study	Deliverables	Type_output	No of output	Target Completion Date
Biostats_deliverables	HEMATOLOGY/ONCOLOGY (H/O)	AAA	abc_123	abc_123_std_001	Study Document Preparation/ Review: SAP creation	SAP (development)	1	1/1/2020

Section 2, Study Related Information:

The second section contains study related information. This section mainly includes study personal name, such as name of lead statistical programmer (SP), lead statistician (ST), clinical programmer (CP), SDTM programmer (if applicable), data manager (DM) and study manager. In addition, whether the work of deliverable is outsourced or not is captured, if yes, then the name of vendor is listed. (see below table 2)

*(Note: those are supportive information mostly used for reference, we will discuss how to capture these data from study metadata repository (MDR) in chapter below as one of new features development)*

**Error! Reference source not found.** Project Metrics Template Design: Section 2 – Study Related Information.

Deliverables	Lead SP	Lead ST	CP	SDTM	DM	Study Manager	Outsourced (Y/N)	Vendor_ name	Comments
Study Document Preparation/ Review: SAP creation	AAA	BBB	CCC	DDD	EEE	FFF	Y	XYZ	.....

Section 3, Resource Prediction Information:

The third section contains resource prediction information. This section includes number of SP (or ST) predicted in order to accomplish each deliverable by targeted completion date. The predication is made by lead SP or ST based on 'type of work', 'amount of outputs' and 'target completion date', and then those numbers will be reviewed and approved by their line managers. Currently, the resources prediction is made monthly across a whole calendar year (see table 3 below).

**Error! Reference source not found..** Project Metrics Template Design: Section 3 – Resource Prediction Information.

Deliverables	Jan 2020	Feb 2020	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020
DB Lock : DB Lock	0.5	0.5	0.5	1	1	1	1	2	2	2	2	2

*Note: numbers are not real and for functional depiction only.*

**2. UNIQUE FEATURES**

In addition to the template design, we build three unique features into our project metrics to support the data entry and summary report.

1. Pull-down list:

The first feature is that we build pre-defined pull-down list for workload related variables as listed in section one. For example, we defined two categories under "Function": "Biostats\_deliverables" or "Programming\_deliverables", and eight categories under "Group": "Hematology/Oncology(H/O)", "Early Development(ED)", "Clinical Pharmacology(CP)", "Immunology/Inflamation(I/I)", "Medical Affairs(MA)", "Solid Tumor(ST)", "Cell Therapy(CAR-T)" and "ADaM Standards(SD)". The pull-down lists of "Compound" and "Study" are extracted from our Biometrics Computing System (BCE), so those information are consistent with real compound and study names. And the pull-down lists of "Deliverables" are pre-defined

by SME from both biostats and programming team. This feature ensures the consistency of data entry from different users.

2. Look-up table:

The second feature is about a look-up table that we created in the background file. The look-up table contains all types of pull-down list and mapping algorithm used in project metrics. This feature allows us to maintain the pull-down list in a single file, meanwhile, by making the look-up table accessible to authorized person only, it avoids accidental changes of any pull-down list by users.

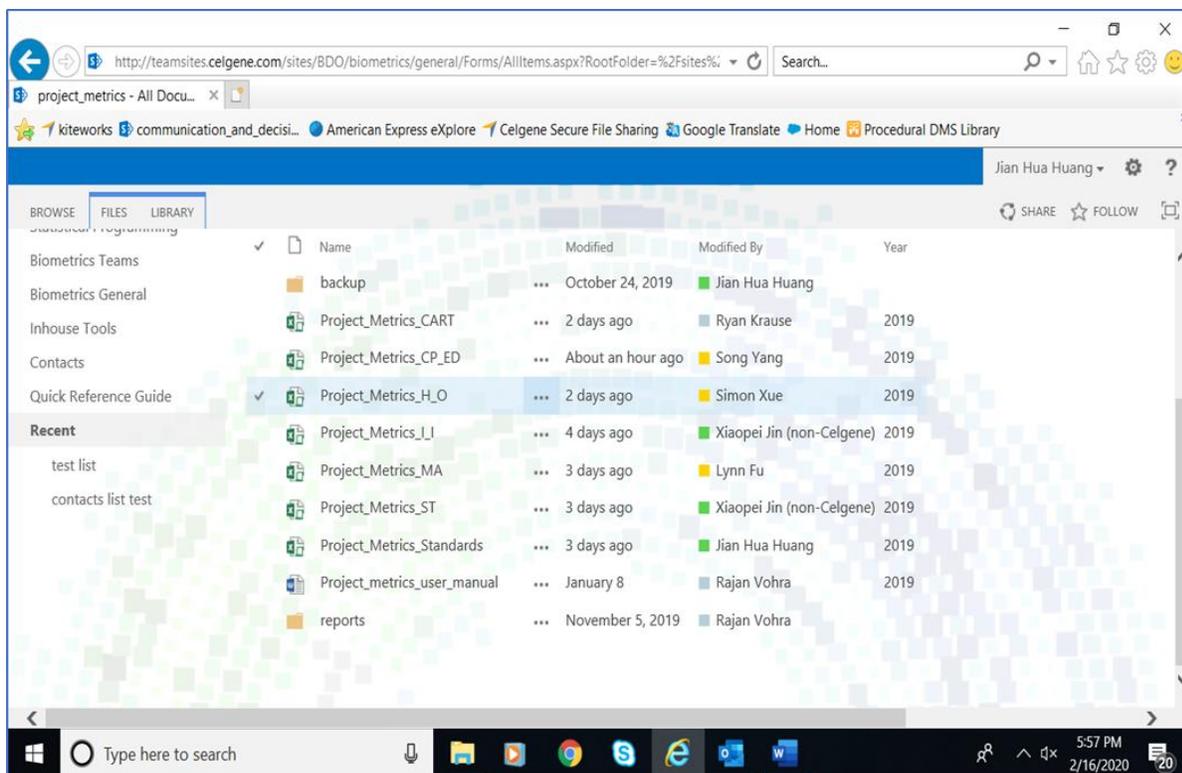
3. Auto-edit check:

The third feature is about multiple auto-edit checks that we added into the project metrics template. For example, the “Number of Output” column allows only positive integer to be entered as valid value; In the “target completion date” column, it requires all date to be entered with format of “dd/mm/yyyy”; furthermore, any variables under section one that are pre-defined by a pull-down list, user must follow the pull-down list for the data entry. This auto-edit check feature ensures the accuracy of data entry and reduces potential data errors and data cleaning time in future.

### **3. OTHERS: FILE LOCATION, DATA ENTRY, USER MANUAL**

To allow the project metrics to be used by many users at the same time, we saved the metrics template on our department SharePoint and split it into 8 individual files (one file per each TA group). Only people granted with SharePoint access can use those files, and they must follow the instruction for data entry. One advantage of using SharePoint is that user must do “check out/check in” to edit files and save changes, this feature allows a file version control, which is especially important for files shared with a large group of users. As an additional support, my team created a user manual with detail instruction and saved the manual in the same location as project metrics, therefore, users could always refer to user manual if they need further help.

Picture 1 – Eight Project Metrics templates and User Manual are saved on SharePoint



## DASHBOARD REPORT

In the next few chapters, we will introduce a series of typical dashboard reports generated by project metrics. Those reports provide leadership team a comprehensive overview and great details of workload assignment and resource planning.

### 1. SUMMARY OF NUMBER OF STUDIES

The first dashboard report is the summary of total number of studies. By default, all studies with Biostats or Programming deliverables captured in the project metrics will be displayed in this report. The number of studies could be displayed per *Functions*, *Group and Compound*, and can be further classified as either *Outsourcing or Inhouse*. This report provides leadership team an overview picture of how many studies are actively having ongoing work and how do these studies distribute under each category (see display 1 below).

Display 1 – Summary of Number of Studies

Summary of No. of Studies	Column Labels		
	Inhouse	Outsourced	Grand Total
Row Labels	0	1	
<b>Biostats</b>			
<b>CELL THERAPY (CAR-T)</b>			

abc_123			
abc_123_std_001	1		1
efg_123			
efg_123_std_001		1	1
efg_123_std_002		1	1
efg_123_std_003		1	1
efg_123_std_004		1	1
efg_456	3	1	3
efg_789	1		1
<b>CELL THERAPY (CAR-T) Total</b>	<b>x</b>	<b>x</b>	<b>x</b>
<b>EARLY DEVELOPMENT (ED)</b>	<b>x</b>	<b>x</b>	<b>x</b>
<b>HEMATOLOGY/ONCOLOGY (H/O)</b>	<b>x</b>	<b>x</b>	<b>x</b>
<b>IMMUNOLOGY/INFLAMMATION (I/I)</b>	<b>x</b>	<b>x</b>	<b>x</b>
<b>MEDICAL AFFAIRS (MA)</b>	<b>x</b>	<b>x</b>	<b>x</b>
<b>SOLID TUMOR (ST)</b>	<b>x</b>	<b>x</b>	<b>x</b>
<b>Biostats Total</b>	<b>x</b>	<b>x</b>	<b>x</b>

*Note: numbers are not real and for functional depiction only.*

## 2. SUMMARY OF NUMBER OF OUTPUTS

The second dashboard report is the summary of total number of outputs. By default, the following types of outputs are displayed: *Number of ADaM datasets, Number of TLG, Number of eSubmission package, Number of SDTM, Number of Study Documentation, Number of Operational related outputs and Others.* And the total number of outputs could be counted per Group, per Compound and per Study. (see display 2 below).

Display 2 – Summary of Number of Outputs

Sum of Number_output	Column Labels							
	1) ADaM	2) TLG	3) eSUB	5) SDTM	6) DOC	7) Operation	8) Other	Grand Total
Row Labels								
<b>Inhouse</b>								
<b>ADAM STANDARDS (SD)</b>	xx	Xxx	xxx	x	x	xx	xx	xxxx
<b>CELL THERAPY (CAR-T)</b>	xx	Xxx	xxx	x	x	xx	xx	xxxx
abc_123	xx	Xxx	xxx	x	x	xx	xx	xxxx
abc_123_std_001	xx	Xxx	xxx	x	x	xx	xx	xxxx
abc_123_std_002	xx	Xxx	xxx	x	x	xx	xx	xxxx
abc_123_std_003	xx	Xxx	xxx	x	x	xx	xx	xxxx
abc_123_std_004	xx	Xxx	xxx	x	x	xx	xx	xxxx
abc_123_pooled	xx	Xxx	xxx	x	x	xx	xx	xxxx
efc_123	xx	Xxx	xxx	x	x	xx	xx	xxxx
<b>CLINICAL PHARMACOLOGY (CP)</b>	xx	Xxx	xxx	x	x	xx	xx	xxxx
<b>EARLY DEVELOPMENT (ED)</b>	xx	Xxx	xxx	x	x	xx	xx	xxxx
<b>HEMATOLOGY/ONCOLOGY (H/O)</b>	xx	Xxx	xxx	x	x	xx	xx	xxxx
<b>IMMUNOLOGY/INFLAMMATION (I/I)</b>	xx	Xxx	xxx	x	x	xx	xx	xxxx
<b>MEDICAL AFFAIRS (MA)</b>	xx	Xxx	xxx	x	x	xx	xx	xxxx
<b>SOLID TUMOR (ST)</b>	xx	Xxx	xxx	x	x	xx	xx	xxxx
<b>Inhouse Total</b>	xx	xxx	xxx	x	x	xx	xx	xxxx

### 3. SUMMARY OF RESOURCE PREDICTIONS & GAPS

The third dashboard report is the summary of resource predictions & gaps. As mentioned before, resources predictions are estimated by lead SP or ST according to the work amount and timeline of each deliverable. Then all resources predicated will be summed up within each Group and presented as the total predicted resources. In addition, the project metrics pulls the actual resources of each Group from the Biometrics employee directory and list those number as current resources in the report. These two types of resources are listed upside and down, the differences are calculated as resources gaps. If predict resources are higher than current resources, it means a shortage of resource. Otherwise, if predict resources are less than current resources, it means a surplus of resources. For example, (see display 3 below), the SD group shows a pretty balance between predicted and current resources; the CAR-T group indicates the shortage of resources across most of the year; and the H/O group shows a surplus of resources in the end of 2020.

Display 3 – Summary of Resource Prediction & Gaps

Row Labels	Sum of Jan'20	Sum of Feb'20	Sum of Mar'20	Sum of April'20	Sum of May'20	Sum of Jun'20	Sum of Jul'20	Sum of Aug'20	Sum of Sep'20
<b>Programming</b>									
<b>ADAM STANDARDS (SD)</b>									
Predicted	6.0	6.3	6.0	6.1	5.8	5.7	6.2	6.3	6.1
Current	6	6	6	6	6	6	6	6	6
<b>GAP</b>	<b>0</b>	<b>-0.3</b>	<b>0</b>	<b>-0.1</b>	<b>0.2</b>	<b>0.3</b>	<b>-0.2</b>	<b>-0.3</b>	<b>-0.1</b>
<b>CELL THERAPY (CAR-T)</b>									
Predicted	36.55	36.05	41.15	43.85	40.85	46.75	45.9	44.4	45.1
Current	38	38	38	38	38	38	38	38	38
<b>GAP</b>	<b>1.45</b>	<b>1.95</b>	<b>-3.15</b>	<b>-5.85</b>	<b>-2.85</b>	<b>-8.75</b>	<b>-7.9</b>	<b>-6.4</b>	<b>-7.1</b>
<b>HEMATOLOGY/ONCOLOGY (H/O)</b>									
Predicted	43.7	59.6	59.8	44.35	42.6	41.4	41.5	30.2	31.7
Current	47	47	47	47	47	47	47	47	47
<b>GAP</b>	<b>3.3</b>	<b>-12.6</b>	<b>-12.8</b>	<b>2.65</b>	<b>4.4</b>	<b>5.6</b>	<b>5.5</b>	<b>16.8</b>	<b>15.3</b>

Note: numbers are not real and for functional depiction only.

## 4. 360 DASHBOARD REPORT

The fourth dashboard report is called '360 dashboard report'. This is the most robust and dynamic report generated by project metrics. As shown in display 4 below, this report includes a core table in the middle of page and multiple parameters table listed around. The core table displays number of key deliverables on a quarterly base across 2020. A click on any of key deliverables (i.e. CSR: CSR) could extend to more granularity levels such as by 'Compound', 'Study' and 'Lead'. In addition, users can subset core tables by clicking on any of parameters table. For example, if the user clicks on one statistician name, then only deliverables which are under that lead statistician will be summarized in the core table. This user-friendly design reports gives users a high flexibility of looking at the summary report at any dimension, therefore we call it as "360 dashboard report".

Display 4 – Summary of 360 Dashboard Report

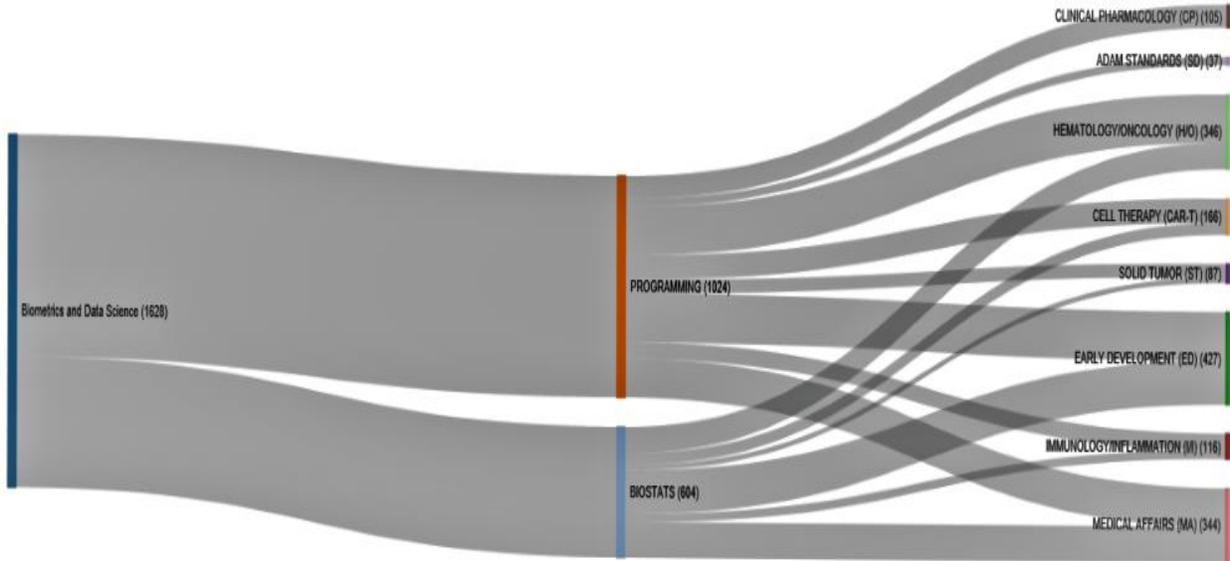
Records	Column Labels			
	2020			
	Q1	Q2	Q3	Q4
Row Labels				
Biostats				
CSR : CSR	XX	XX	XX	XX
DB Lock : DB Lock	XX	XX	XX	XX
Dry Run : Dry run (final)	XX	XX	XX	XX
Interim Analysis : DMC	XX	XX	XX	XX
Interim Analysis : Interim analysis	XX	XX	XX	XX
Primary Publication : Development and Review	XX	XX	XX	XX
Regulatory Request : FDA request	XX	XX	XX	XX
Regulatory Request : JNDA	XX	XX	XX	XX

Note: numbers are not real and for functional depiction only.

## 5. SANKEY DIAGRAM

The latest report we developed is called 'Sankey Diagram'. This is the report that uses innovative technology, where we applied Sankey Diagram design (and code) into project metrics data summary. As shown in display 5 below, the Sankey Diagram could present the number of deliverables per multiple dimensions (i.e. Function, Group or Compound), in addition, it displays the distribution of workload from one dimension to the others, therefore, it provides a true dynamic picture by bringing all related dimension together into one diagram.

Display 5 – Sankey Diagram



## **FUTURE DEVELOPMENT**

With its thorough template design and robust reporting tools, the project metrics provides the leadership team valuable information on workload management and resource planning. However, during the implementation of project metrics, we found some challenges which are mostly associated with data entry and data cleanings. Therefore, we think about new feature developments for the project metrics in below.

### **1. MOVE PROJECT METRICS FROM SHAREPOINT TO WEBSITE.**

Our current project metrics is located on department SharePoint. It does provide a centralized file location for data entry and collection. However, SharePoint requires user to check out file each time for editing, and then check in the file to save changes. Once the file is checked out, it is locked by that user and not editable by other users until the file is checked in. This is inconvenient as the file is shared by a large group of users. Moving the project metrics to website could resolve this issue. As anyone could logon to the file at the same time and save their changes simultaneously. Another significant advantage of using Web base project metrics is that it will be more powerful and flexible for the control of data entry. As mentioned before, the quality of our report relies heavily on how user enter the data, Although we tried multiple ways of improving data entry, such as provide user manual, instructions, training and create auto edit-check, we think it will be most effective by moving project metrics from SharePoint to Website.

### **2. COLLECT DATA DIRECTLY FROM METEDATA REPORSITORY (MDR).**

In future, some variables in project metrics may no longer need to be entered by users. For example, the study supportive information in section two are usually shared with other database and could be pulled out from company Mega Data Repository (MDR). If this new feature is added, it could significantly reduce the time of data entry and improves the data accuracy as well. More importantly, pulling data from MDR will ensure that the most updated information will be used in project metrics, and ensure the data consistency between project metrics and other types of company reports which share the same data from MDR.

### **3. CREATE STANDARD BUILT-IN FORMULA FOR RESOURCE PREDICATION.**

In addition to workload management, resources planning is another important feature of project metrics. The resource planning is based on resource predication, which is done by lead SP or ST according to the workload and timeline of each deliverable. Currently, there is no standard formula of resources calculation, so it is a subjective judgement by each lead SP/ST and their managers. This may cause discrepancy on resources planning across different Group, even the amount of workload and timeline are similar. There are needs to create built-in standard formula, so the predict metrics could auto calculate resources predication base on type of work, amount of work and targeted timeline. Then both lead SP or ST and mangers could review and adjust the resource prediction to be more realistic. This new feature, if implemented, could further reduce the burden of data entry of project metrics and improves data entry compliance rate among all users.

## CONCLUSION

The project metrics is considered as a useful tool for Biostats & Programming leadership team to conduct workload management and resources planning. The metrics has a thorough design which collects work deliverable related information and resources prediction according to type of work, amount of work and estimated timeline. In addition, the metrics builds robust reporting system which can generate dynamic, multiple styles and user-friendly summary reports. Those reports allow leadership team to check workload distribution at different dimensions and view the resources planning across all each Group. Some challenges are found during data entry and data cleaning of project metrics, to address those findings, three new features are proposed and listed as future development plan. Overall, this tool could support Biostats & Programming leadership team for a successful workload management and resources planning.

## CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Daniel Huang  
BMS  
Phone: 908-679-7933 (office)  
[jjhuang@celgene.com](mailto:jjhuang@celgene.com)

Rajah Vohra  
BMS  
Phone: 908-679-7432 (office)  
[rvohra@celgene.com](mailto:rvohra@celgene.com)

Andy Chopra  
BMS  
Phone: 908-897-7217 (office)  
[anchopra@celgene.com](mailto:anchopra@celgene.com)

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