

## **Quality, Timely and Within Budget Analysis and Reporting – Yes, you can have all three! A process and tool to help achieve this goal**

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### **ABSTRACT**

As the cost of conducting clinical trials is skyrocketing in today's competitive climate, the Pharma and the Biotech industries are stressing better efficiency, more precise resource forecasting, and tighter budgeting. The key to success is to implement efficient processes to allocate, monitor, and manage budgets and resources. In addition, early planning of analysis and reporting tasks and the resources to support those tasks is crucial. These provide a roadmap to operate efficiently and avoid uncontrolled changes to project scope, therefore enabling organizations to be cost-effective.

To create accurate timelines and realistic budgets, the analysis and reporting requirements must be fully defined. It is important to have a complete understanding of the scope of the tasks in the preliminary stages of budgeting in order to set accurate budgets. Otherwise, significant changes to requirements will require significant modifications to the initial budgets.

At Alcon, Statistical Programming Therapeutic Area Leads are responsible for the budgeting and resource forecasting for data analysis and TFL reporting for studies and projects. The project team is responsible for delivering quality outputs in a timely manner within the budget. In this paper the authors will describe the process which the Alcon Statistical Programming group developed to estimate budgets, allocate resources and establish the schedule of activities. Also, this paper includes the process to monitor the progress of the project activities which enables the team to mitigate any risks and successfully complete the programming of analysis and reporting tasks with high quality, on-time and within the approved budget.

### **INTRODUCTION**

Recently, more and more pharmaceutical and biotech organizations are challenging Statistical Programming departments to deliver quality outputs within pre-approved budgets and very aggressive timelines. While some factors that affect these outcomes, such as scope changes, are not in their control, programming teams can focus on managing factors that are within their control and mitigate any risks that could negatively impact planned schedules and budgets. It is often challenging to obtain the necessary project information to determine the actual scope of work. As a result, managers are not equipped to make informed decisions such as whether to add resources to meet planned schedules and metrics which are critical to ensure successful project implementation.

The focus of this paper is to provide the managers and lead programmers with a process and tools to help plan, monitor and manage analysis and reporting activities. The same process and set of tools can be used by the project team to track and monitor the progress of the project. In this paper, we will discuss how to forecast long-term resource needs to ensure that resources are available to meet demanding reporting milestones. We will also discuss how to estimate budgets and come up with realistic timelines based on actual requirements.

As early as the planning stage, we develop the project tracker. This tracker is very valuable during the planning, development and execution of activities. The project tracker is a very useful tool as it provides an organized way to collect project information and summarize the actual status of the project. This paper includes a detailed discussion and examples of how to populate a project tracker and how to use the various components such as the dashboard to review budgets and track the progress of the project and provide top-line information to management.

## LONG TERM RESOURCE PLANNING

Long term planning of resources is important because in the pharmaceutical industry, finding qualified programmers with the right skills is challenging. It is therefore critical to identify any resource gaps in advance to give ample time to secure additional resources if needed, or to address any oversupply to avoid unnecessary costs. The initial stage of budgeting starts at Alcon when protocol synopsis is approved. A baseline budget can be determined depending on the study complexity based on the protocol synopsis and similar studies completed previously in the same therapeutic area.

We use the complexity of the study as a guide to estimate the resources and the budget. Setting an average complexity to a study with a specific scope gives us flexibility to estimate resources and budget for those studies with higher or lower complexity than average. For example, as shown in Table 1, an average study with complexity of 1 may require 1200 programming hours to generate 10 datasets, 65 tables, 25 listings and 10 figures. Any study with higher complexity than average can be assigned a complexity > 1 and any study with lower complexity than average study can be assigned complexity < 1. In the absence of the SAP and TFL shells, it is challenging to estimate the efforts when the actual requirements are unknown. However, statisticians may have information about the study requirements. In addition, they would know if the study is similar to any previously completed studies in terms of the nature of the analyses and the number of outputs needed. Having a reference complexity 1 makes it easy to set meaningful baseline budgets by using the available information from the completed studies. Once the study complexity is assigned and the number of hours needed for programming activities is determined, we use the programmer's average hourly rate to determine the baseline study budget.

Study Complexity	Study A 0.8	"Average" Study 1.0	Study B 1.2
Hours	960	1200	1440
Number of outputs:			
Datasets	8	10	12
Tables	52	65	78
Listings	20	25	30
Figures	8	10	12

**Table 1: Baseline hours based on study complexity**

To increase the accuracy of the long term forecasts, we use study milestones to break down the programming development hours by month, based on when specific programming activities will occur with reference to First Patient First Visit, Database Lock (DBL) or other study milestones. Table 2 shows a sample monthly breakdown of baseline programming hours. The algorithm for the breakdown can be defined and a SAS code can be developed to generate monthly programming time estimates for all studies in the pipeline. A SAS code can also be developed for budget tracking to compare these estimated hours to the actual hours spent.

Task	Programming Timeline							
	-4 Months	-3 Months	-2 Months	-1 Month	DATABASE LOCK	+1 Month	+2 Months	Total
Review study documents (SAP, TFL Shells, etc.)	40							40
Create Validation Plan	22							22
Create Analysis Dataset Specifications	80							80
Datasets Programming	80	80						160
TFLs Programming		295	295					590
Dry Run and Validation Findings				80				80
DBL Activities					100			100
Post-hoc Requests for CSR						20	20	40
Folder Setup	8							8
Randomization	40							40
Management of Activities	7	7	7	7	7	3	2	40
<b>Total</b>	<b>277</b>	<b>382</b>	<b>302</b>	<b>87</b>	<b>107</b>	<b>23</b>	<b>22</b>	<b>1200</b>

**Table 2: Monthly breakdown of baseline hours**

Once the complexities have been assigned for all studies in the pipeline, we determine the number of hours and overall budget along with the required number of resources (FTEs) as shown in Table 3. For more precise resource forecasting, we also include project related activities such as anonymization, safety and efficacy integration analyses and other regulatory requirements.

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Protocol	DBL	Complexity	# Hours	Jan-2016	Feb-2016	Mar-2016	Apr-2016	May-2016	Jun-2016	Jul-2016	Aug-2016	Sep-2016	Oct-2016	Nov-2016	Dec-2016
Study A	2/1/2016	1.0	1200	302	107	23	22								
Study B	4/11/2016	0.7	840	234	185	55	107	23	22						
Study C	5/24/2016	1.0	1200	277	382	302	87	107	23	22					
Study D	6/10/2016	0.8	960		235	283	224	66	107	23	22				
Study E	6/28/2016	1.0	1200		277	382	302	87	107	23	22				
Study F	7/19/2016	0.7	840			214	234	185	55	107	23	22			
Study G	8/16/2016	2.0	2400				488	877	691	192	107	23	22		
Study H	10/8/2016	1.0	1200						277	382	302	87	107	23	22
Study I	10/26/2016	1.25	1500						330	506	399	113	107	23	22
Study J	12/9/2016	1.0	1200								277	382	302	87	107
Study K	12/16/2016	1.0	1200								277	382	302	87	107
<b>Total Hours Needed</b>				<b>511</b>	<b>1079</b>	<b>1236</b>	<b>1442</b>	<b>1345</b>	<b>1612</b>	<b>1255</b>	<b>1429</b>	<b>1009</b>	<b>840</b>	<b>220</b>	<b>258</b>
<b>Total FTEs Needed</b>	<b># Hours per Month:142</b>			<b>4</b>	<b>8</b>	<b>9</b>	<b>10</b>	<b>9</b>	<b>11</b>	<b>9</b>	<b>10</b>	<b>7</b>	<b>6</b>	<b>2</b>	<b>2</b>

Table 3: Long term resource forecasts

## ESTIMATING THE ACTUAL BUDGETS

When the SAP and the TFL shells become available, we look at the number of outputs needed and the type and complexity of the outputs. At this stage, it is important to have the mature analysis requirements in order to set realistic budgets to avoid the additional costs of unnecessary rework. Based on these requirements, we estimate the number of hours needed to deliver all the final outputs using standard timelines for different programming tasks. Standard timelines are defined based on the type and complexity of the output. The estimated number of hours needed to create and validate an output depends heavily on the organization’s use of standards such as standardized TFL shells, datasets and reusable codes. The standard timelines shown in Table 4 assumes minimum number of standard tools and programmers make use of the reusable codes from completed studies.

Task	Lead Programmer	Program Development	Independent Validation
<b>Analysis Dataset Specifications</b>			
Simple	6	-	-
Complicated	8	-	-
<b>Datasets Programming</b>			
Simple	-	6	6
Complicated	-	10	10
<b>Table Programming</b>			
Simple - 1 table design, all cuts	-	4	4
Complicated - 1 table design, all cuts	-	8	6
Replicate	-	2	2
Rerun	-	1	1
<b>Figure Programming</b>			
Simple - 1 Figure design, all cuts	-	4	4
Complicated - 1 Figure design, all cuts	-	8	4
Replicate	-	2	2
Rerun	-	1	4
<b>Listing Programming</b>			
Simple/Complicated - 1 listing, all cuts	-	3	2
Replicate	-	2	2
Rerun	-	1	1

Table 4: Standard timelines based on type and complexity of output

The efforts for some tasks such as the review of study documents, creating the validation plan and folder setup are estimated with a fixed number of hours for all the studies. These estimates are added to the study level programming hours calculated based on the number of datasets and outputs needed to complete the analysis. Display 4 illustrates how this is done to get the actual hours for a sample study. Once the actual hours are determined, we use the average hourly rate of the programmer to calculate the actual budget. This actual budget is compared with the baseline budget. If the actual budget is less than or more than a certain threshold of the baseline budget, a re-baseline of the budget is needed.

## ALLOCATION OF RESOURCES TO PROJECT

The actual allocated hours with breakdown of different tasks (lead programmer, program development, independent validation, etc.) are submitted to the resource manager. Resources are assigned based on the skillsets needed for the tasks, prioritizing programmers with experience in similar projects. Once the structure of project team is known, a schedule of activities is developed considering the earliest availability of resources. Table 5 shows an example of detailed schedule of activities. The dependencies of the activities must be carefully studied and projected completion dates must be set for each activity in order to gain maximum efficiency.

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Program	Output	Program Development				Independent Validation			
		Developer	Projected Completion Date	Status	Date Completed	Validator	Projected Completion Date	Status	Date Completed
study-md-dataset1	dataset 1	P1	22-Dec-15	Complete	23-Dec-15	P4	5-Jan-16	Complete	5-Jan-16
study-md-dataset2	dataset 2	P1	5-Jan-16	Started		P4	11-Jan-16	Started	
study-md-dataset3	dataset 3	P2	7-Jan-16	Complete	8-Jan-16	P5	12-Jan-16	Pending	
study-mt-table1	table 1	P3	31-Dec-15	Complete	30-Dec-15	P6	5-Jan-16	Complete	4-Jan-16
study-mt-table2	table 2	P3	5-Jan-16	Complete	5-Jan-16	P6	11-Jan-16	Started	
study-mt-table3	table 3	P1	7-Jan-16	Started		P4	12-Jan-16	Pending	
study-ml-listing1	listing 1	P1	8-Jan-16			P4	13-Jan-16		
study-ml-listing2	listing 2	P2	8-Jan-16	Started		P5	13-Jan-16	Started	
study-mf-figure1	figure 1	P3	7-Jan-16	Started		P6	12-Jan-16		

**Table 5: Sample schedule of activities**

## MONITORING AND MANAGING TASKS AND RESOURCES USING A PROJECT TRACKER

The project tracker is a tool that provides the following:

1. dashboard for a quick review of the project status
2. method to determine if the budget needs to be re-baselined
3. detailed list of all required outputs and the status of each individual output
4. resource assignments for each output, primary and validation
5. validation findings and resolution
6. any other requested activities

The project tracker provides management with a high level status of the project progress and individual output level information if more details are needed. This tool helps lead programmers estimate and assign the resources and aids with the communication among programmers and statisticians. The programming tracker is a dynamic tool that can be adjusted as needed during the programming development. It provides information on individual level accountability for the outputs as well as the status on budget. We often experience scope change and ad-hoc requests for the projects still under development. The project tracker helps document these changes and provide the information on additional hours and resources spent on these ad-hoc requests. This helps the lead programmer to justify any additional resource requests and explains the discrepancies between the planned and actual budgets.

## POPULATING THE PROJECT TRACKER

Populating the tracker is the first step. There are 3 main sections to populate: Plan, DTFL (datasets and TFLs) and Estimates. Each of these sections is discussed below.

### Populate the Project Plan

This section contains a condensed view of the overall project. You will need to determine the major project steps for your process, the amount of time it takes to complete those steps and resources responsible for completing those steps. Display 1 shows an example of a populated plan.

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Project:	xxxx1234_xxx_x12345	Pattern:	PS: John Smith (JS)	Lead: Kelly Doe (KD)	RD: CP:
Indication:	protocol12345	TS:	John Doe (JD)	PP: Person One (P1), Person Two (P2), Person Three (P3)	
DBL:	3/2/2016	SCE:	Amy Smith (AS)	VP: Person Four (P4), Person Five (P5), Person Six (P6)	
Notes:	DRY RUN: 2/3/16, 2 data transfers - after lock				

  

Tasks	Target Date	Metrics	Resource	Status	December			January				February				March				
					7	14	21	28	4	11	18	25	1	8	15	22	29	7	14	21
<b>Project/Analysis Task Area Setup</b>	<b>11/1/15</b>	8h	PS, RD, ITS, All		x															
<b>Kick-off Meeting</b>	<b>12/15/15</b>		All	Complete	x															
<b>SAP and Reporting Plan</b>	<b>11/19/15</b>	4m<DBL		Complete																
TFL Shells	11/19/15		TS	Complete																
Create TFL Tool Worksheet - Stat	11/19/15		TS	Complete																
<b>Tracking Sheet</b>	<b>12/10/15</b>	3d>Docs	Lead	Complete	x															
<b>EDC/External/Treatment Data Structure</b>			CP, RD																	
<b>SAS Program Validation Plan</b>	<b>12/11/15</b>	5d>Docs		In Progress	x															
Complexity Assessment	12/9/15		TS, PP	Complete	x															
Validation Planning	12/9/15		Lead, PP	In Progress	x															
Create Validation Plan	12/10/15		PP	In Progress	x															
Review Validation Plan	12/11/15		TS, VP, PP		x															
Approve Validation Plan	12/11/15		TS, VP, PP		x															
<b>SAS Program Specifications</b>	<b>1/8/16</b>	30d>Docs								x										
Review TFL shells / notes for completeness	12/10/15		PP	In Progress	x	x														
Create program specifications	12/1/15		TS/PP	None at this time																
Create data specifications	1/6/16		PP	In Progress	x	x	x	x	x											
Update TFL Tool Worksheet - Prog	12/10/16		PP	Complete	x															
Review Specifications	1/7/16		TS, PP							x										
Approve Specifications	1/8/16		TS, PP							x										
<b>Load EDC/External/Treatment Data</b>			CP, RD		x					x	x				x					
<b>Create Validated Code</b>	<b>2/3/16</b>									x	x	x	x							
Meet with PP to review data specifications	12/14/15		PP		x															
Data sets	1/15/16		PP, VP			x	x	x	x	x	x	x								
Meet with VP to review TFL requirements and validation plan	1/4/16									x										
TFLs	2/3/16		PP, VP							x	x	x	x							
<b>Dry Run and Validation Findings</b>	<b>2/3/16</b>	1m<DBL	All																	
<b>DBL</b>	<b>3/2/16</b>		All																	
<b>FIR</b>	<b>3/3/16</b>	1d>DBL	All																	
<b>TFLs</b>	<b>3/14/16</b>	8d>DBL	All																	x

### Display 1: Sample Plan Populated

The major process steps are bolded with red dates while any notable supporting steps are also listed but not otherwise emphasized. The Metrics column should contain the standard cycle times for your process. Instead of actual resource initials, the role initials are used to identify who is responsible for each step. In this example, the Tracking Sheet (4<sup>th</sup> major process step) should be completed by the Lead within 3 days of receiving the necessary documentation from the statistician. The Plan is used to review all activities leading up to the generation and validation of dataset and TFL programs and outputs. Those are tracked in detail in DTFL part of the tracker.

### Populate DTFL (Datasets and TFLs)

Each dataset and each TFL is tracked. Display 2 provides an example of a populated D section and Display 3 provides an example of a populated T section. The Lead is responsible for determining program and output names, assigning resources to each item, and determining due dates. At Alcon, we have implemented standard naming conventions for our programs and outputs. We have found this makes it easier to move between projects. We have also implemented the use of an independent programmer as our validation method. Depending on your validation method, you may or may not need to use the Independent Validation area. At Alcon, we have a development area and a production area. For this reason, we track both separately. Again, depending on your process, you may or may not need to use the Production columns.

Type	Group	Program	Dataset	Data Domain	S	C	Validation	Program Development				Independent Validation		Production			
								Devel oper	Projected Completion Date	Status	Date Completed	Production	Valida tor	Projected Completion Date	Status	Date Completed	Production
D	GP	protocol12345-gp-md-adsf	adsl	dm001,ds001,ds002,ie001,ae001,ex001,xs001,vs002,protocol12345tr	1	1	DP	P1	31-Dec-15	Complete	30-Dec-15	1	P4	5-Jan-16	Complete	5-Jan-16	1
D	GP	protocol12345-gp-md-adacct	adacct	adsl,lm6362201tr,v,isdad001,ss001,ss002	1	1	DP	P1	5-Jan-16	Complete	2-Jan-16	1	P4	10-Jan-16			
D	GP	protocol12345-gp-md-aobat	aobat	adsl,adacct,dispense,dispo	1	1	DP	P2	7-Jan-16	Pending			P5	12-Jan-16	Pending		
D	EF	protocol12345-ef-md-addev	addev	adsl,adacct	1	1	DP	P2	8-Jan-16	Started			P5	13-Jan-16			
D	EF	protocol12345-ef-md-adv asq	adv asq	adsl,adacct,qs001,qs002	1	1	DP	P3	7-Jan-16				P6	12-Jan-16			
D	EF	protocol12345-ef-md-adeff	adeff	adsl,xx001	1	1	DP	P1	7-Jan-16				P4	12-Jan-16			
D	SF	protocol12345-sf-md-adae	adae	adsl,ae001	1	1	DP	P2	9-Jan-16	Complete	1/5/2016		P5	14-Jan-16			
D	SF	protocol12345-sf-md-adcm	adcm	adsl,cm001	1	1	DP	P3	8-Jan-16				P6	13-Jan-16			
D	SF	protocol12345-sf-md-admh	admh	adsl,mh001	1	1	DP	P3	9-Jan-16				P6	14-Jan-16			
D	SF	protocol12345-sf-md-adiop	adiop	adsl,adacct,y001	1	1	DP	P3	10-Jan-16				P6	15-Jan-16			

### Display 2: Sample D (Datasets) Populated

The gray section is where you will provide information about the datasets: name, sources, etc. The yellow section is where you determine if the dataset is Simple (S) or Complicated (C). A complicated dataset will allow for more working hours than a simple one. The blue and green sections are for Primary and Validation assignments and status tracking. The assigned programmers are responsible for populating the Status, Date Completed and Production columns. We recommend that each programmer takes a few minutes each day to update their status.

Not pictured here are a section for the statistician to review the output and a section for comments. Comments are useful to relay information to other team members such as the reasons why a status is pending. For example, the

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source data may not be available.

Type	Shell	Section Num	ID	Title2	Title3	Title4	Program	FileName	Source	ID	10 9 2 44				Program Development 2				Independent Validation 1										
											S	C	R	run	Validat	Devel	oper	Projected Completion Date	Status	Date Completed	Produ	ction	Valid	ator	Projected Completion Date	Status	Date Completed	Produ	ction
T	P	1	& ENRL	Table 1			protocol12345-gp-mt-dsp	protocol12345-gp-mt-dsp	adsl	DISP		1		DP	P1	8-Jan-16	Complete	29-Dec-15	1	P4	13-Jan-16	Complete	30-Dec-15	1					
T	P	2	& RAND	Table 2			protocol12345-gp-mt-inv-rand	protocol12345-gp-mt-inv-rand	adsl	INVRAND		1		DP	P1	9-Jan-16	Complete	29-Dec-15	1	P4	14-Jan-16	Pending							
T	P	3	& ENRL	Table 3			protocol12345-gp-mt-scmfail	protocol12345-gp-mt-scmfail	adsl	SCORNFALL		1		DP	P2	10-Jan-16	Complete	4-Jan-16		P5	15-Jan-16	Pending							
T	P	4	& RAND	Table 4			protocol12345-gp-mt-ex cl	protocol12345-gp-mt-ex cl	adsl	EXCL		1		DP	P2	11-Jan-16	Pending			P5	16-Jan-16	Pending							
T	P	5	& RAND	Table 5			protocol12345-gp-mt-pop	protocol12345-gp-mt-pop	adsl	POP		1		DP	P3	11-Jan-16	Complete	2-Jan-16		P6	16-Jan-16	Complete	5-Jan-16						
T	P	6	& RAND	Table 6			protocol12345-gp-mt-dev	protocol12345-gp-mt-dev	addev	DEV		1		DP	P3	12-Jan-16	Started			P6	17-Jan-16								

### Display 3: Sample T (Tables) Populated

The sections for T, F and L are the same as with D. However the gray and yellow sections are slightly different. In the gray section, there are several more columns. At Alcon, we have implemented a TFL tool that uses text ID values based on the filename and also groups the TFLs into sections. The TFL tool also contains a unique numeric ID value for each TFL. The ID Num column contains this unique numeric ID value. This allows us to easily move between the TFL tool and the project tracker. Based on your process, you may or may not need to use these particular columns: Section, ID Num, ID. While you may not need to move between different TFL sources, using a unique numeric ID for each output is still a good idea to maintain a fixed identifier for the output.

The yellow section is where you will determine the type of output: Simple (S), Complicated (C), Replicate (R), and Re-run. A replicate is a program that is very similar to another program, but has a few differences. For example, the first program produces output for each treatment in columns. The second program also produces output for each treatment in columns, but it also has a total column. Since a portion of the programming is completed in the first program, the second program (replicate) should take less time to complete. A re-run is an output that is produced from the same program as another output using a macro call. For example, you need to produce a demographic table for 2 different populations. You would program the output and make the population selection a macro variable. So there is one program with 2 macro calls. The second output would be a re-run.

The blue and green sections are exactly the same as previously mentioned. Again, not pictured are sections for the statistician and comments.

F (Figures) and L (Listings) are populated in the exact same manner as T (Tables).

### Populate Estimates

Estimates are used to determine how many hours the project will need to be completed successfully. If you have a condensed timeline, you will need more resources for a short period of time. If you have the luxury of time, you can use fewer resources over the longer timeframe. But in the end, the project will still need the same number of total hours.

You will need to determine how many hours will be needed for each task or output type. Display 4 provides an example of project estimates.

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Programming Timeline Standards				protocol12345				
Task	Estimated Hours			# Programs			Total # Hours	
	PP	VP Manual	VP DP	PP	VP Manual	VP DP	PP	VP
<b>Project/Analysis Task Area Setup</b>	5		3				5	3
<b>SAS Program Specifications</b>								
Review of SAP and TFL shells	16			Standard			16	
TFL Specifications	16			Standard			16	
Update TFL Tool worksheet	8			Standard			8	
<b>Data specifications</b>								
Simple	6			5			30	
Complicated	8			5			40	
Review / Revisions	2			Standard			2	
Review and Approve all the documents	8			Standard			8	
<b>SAS Program Validation Plan</b>								
Complexity Assessment	2			Standard			2	
Create Validation Plan	16			Standard			16	
Review and Approve	4			Standard			2	2
<b>Database Programming</b>								
Simple	6	6	6	5	0	5	30	30
Complicated	10	6	10	5	0	5	50	50
<b>Table Programming</b>								
Simple - 1 table design, all cuts	4	6	4	10	0	10	40	40
Complicated - 1 table design, all cuts	8	6	6	9	0	9	72	54
Replicate	2	6	2	2	0	2	4	4
Rerun	1	6	1	44	0	44	44	44
<b>Figure Programming</b>								
Simple - 1 Figure design, all cuts	4	4	4	0	0	0	0	0
Complicated - 1 Figure design, all cuts	8	4	4	2	0	2	16	8
Replicate	2	4	2	0	0	0	0	0
Rerun	1	4	4	8	0	8	8	32
<b>Listing Programming</b>								
Simple/Complicated - 1 listing, all cuts	3	2	2	13	0	13	39	26
Replicate	2	2	2	0	0	0	0	0
Rerun	1	2	1	12	0	12	12	12
<b>Others</b>								
Dry Run and Validation Findings	40		40	Standard		Standard	40	40
<b>Total Hours (Datasets and TFLs)</b>							<b>500</b>	<b>345</b>
TALSP Hours							40	
DBL Activities							30	70
Randomization							24	16
Data Transfers - PK/IMM							40	20
CSR							20	20
Submission Activities								
<b>Total Hours (All Activities)</b>	<b>1125</b>						<b>654</b>	<b>471</b>
<b>FTE hours per month</b>	<b>142</b>							
<b>Project timelines in months</b>							2	2
One FTE hours							284	284
<b>Total # of FTEs needed</b>							<b>1.8</b>	<b>1.3</b>

#### Display 4: Sample Estimates Populated

The peach section is where you will determine the number of hours you want to devote to each task or output type. The green section is where you will determine if any of your outputs will be validated manually. You will need to populate these values. The other values in this area will be automatically populated based on inputs from the DTFL sections.

Below the Datasets and TFLs section is an area for other activities for the project. You will need to determine what these additional activities are for your process and populate the hour estimates as well.



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<b>Overall:</b>		<b>Development</b>		<b>Production</b>	
<b>Total N</b>		<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>Datasets:</b>	10	1	10%	1	10%
<b>All TFLs:</b>	100	2	2%	1	1%
<b>Unique TFLs:</b>	36	2	6%	1	3%

  

<b>Datasets Detail:</b>		<b>Total</b>	<b>Not Started</b>		<b>Started</b>		<b>Pending</b>		<b>Complete</b>		<b>Production</b>	
			<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>Primary Validation Stat</b>		10	5	50%	1	10%	1	10%	3	30%	2	20%
		10	8	80%	0	0%	1	10%	1	10%	1	10%
		10	10	100%	0	0%	0	0%	0	0%		

  

<b>TFLs Detail:</b>		<b>Total</b>	<b>Not Started</b>		<b>Started</b>		<b>Pending</b>		<b>Complete</b>		<b>Production</b>	
			<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>Primary</b>	<b>Total TFLs</b>	100	80	80%	1	1%	3	3%	16	16%	4	4%
	<b>T</b>	65	59	91%	1	2%	1	2%	4	6%	2	3%
	<b>F</b>	10	0	0%	0	0%	0	0%	10	100%	0	0%
	<b>L</b>	25	21	84%	0	0%	2	8%	2	8%	2	8%
<b>Validation</b>	<b>Total TFLs</b>	100	88	88%	1	1%	9	9%	2	2%	1	1%
	<b>T</b>	65	58	89%	0	0%	5	8%	2	3%	1	2%
	<b>F</b>	10	9	90%	1	10%	0	0%	0	0%	0	0%
	<b>L</b>	25	21	84%	0	0%	4	16%	0	0%	0	0%
<b>Stat</b>	<b>Total TFLs</b>	100	100	100%	0	0%	0	0%	0	0%		
	<b>T</b>	65	65	100%	0	0%	0	0%	0	0%		
	<b>F</b>	10	10	100%	0	0%	0	0%	0	0%		
	<b>L</b>	25	25	100%	0	0%	0	0%	0	0%		

**Display 6: Dashboard Detail Review**

This view is useful to determine if there is a particular area that might have some issues. Once an area is complete, the dashboard will automatically shade the cell green. The overall part of this section of the dashboard also splits the TFLs into total counts as well as unique program counts. This is especially helpful when you have several programs than generate many outputs.

The final piece of the dashboard provides some insight into the project scope.

<b>Historical Totals:</b>	<b>Date</b>	<b>Complexity</b>	<b>Datasets</b>	<b>TFLs</b>	<b>T</b>	<b>F</b>	<b>L</b>
<b>At Protocol Effective:</b>	6/1/2015	0.5	5	50	33	5	12
<b>At Initial Tracker:</b>	12/10/15	0.75	8	75	49	7	19
<b>Final:</b>		0.95	10	100	65	10	25
<b>% CHG from Protocol Effective</b>		89%	100%	100%	97%	100%	108%
<b>% CHG from Initial Tracker</b>		26%	25%	33%	33%	43%	32%

**Display 7: Dashboard Project Scope**

At Alcon, we assign a complexity to a project to determine the initial budget at protocol effective. We do this because we often do not have the true scope of work until much closer to database lock.

It is important to keep track of how the scope of work changes throughout the project life cycle. The At Protocol Effective and At Initial Tracker lines are manually populated. The Final line is populated automatically from the DTFL sections. More times than not, the scope of work changes during the project life cycle. If a project is running late or is over budget, here is where you might find evidence of why. In the example above, you can see there are 25% more

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datasets and 33% more TFLs than planned when the tracker was created.

## DTFL

While the project is ongoing, the DTFL sections can be monitored to determine if assignments need to be shifted. It's possible that one programmer may complete their tasks early while another programmer may be struggling.

## Validation Log

The validation team keeps a list of findings they have identified. To keep the spirit of the independent validation, it is best if the primary and validation programmers communicate objectively with each other. Using the log facilitates proper communication and can provide some lessons learned that can be applied in the next project. Display 8 is an example of a populated validation log.

Issue Identification							Issue Resolution				
Issue #	Type	TFL #	Title	Issue	Date Found	Reported by	Priority (H/M/L)	Person Responsible for Resolution	Root Cause	Actual Resolution (if different from plan)	Date Resolved
1	D		ADSL	FASFL flag - According to the logic, we should not consider USV and Early exit? but in the dataset they are flagged as 'Y' instead of 'N'	20-Jan-16	P1	H	P4		Spec updated to consider USV and EE	29-Jan-16
2	D		ADACCT	Differences between Primary and Validation re: imputing the 'Discontinued' Visit	20-Jan-16	P2	M	P5		Spec updated for STATVST variable. Subject status for visits on or after visits should populate 'DISCONTINUED'	29-Jan-16
3	D		ADIOP	Derivation of the SEYEP and SEYEPN variable is different in the primary side. As per spec we have to assign SEYEP=EXEYE if EXEYE in 'OS'/'OD' and we have to follow the specification rules for EXEYE='OU' records	21-Jan-16	P1	M	P4	SEYEP definition was not very clear. After talking with Primary and Statistician, now it is clear.	The program is modified accordingly to reflect the correct definition of SEYEP/SEYEPN.	22-Jan-16

### Display 8: Sample Validation Log

The validation programmer populates the issue and the primary programmer is responsible for populating the resolution information. If the primary and validation programmers cannot reach a resolution, the lead and/or the statistician must provide guidance.

## Other Activities

Other activities document any additional work that has been requested. It can also document any major changes to approved TFL shells such as when a single output needed to be programmed twice because of changes in specifications. This section can also provide insight if the project gone over budget or is running late. Display 9 is an example of an other activity.

Date	Activities / Requests	Programming Tasks	# Hours-PP	# Hours-VP	Notes
6-Jan-16	Spreadsheet of subjects that are potentially given rescue treatment	Pull all data for subjects that appear in the unblinding file	20	0	

### Display 1: Sample Other Activity

## Status Meeting

The status meeting section provides a means to track any significant vacation or other resource unavailable periods. This section also maintains a running list of action items for the team. Displays 10 and 11 reveal the support tools to aid during status meeting.

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PTO													Meeting					
Resource	December				January				February				March				Attendance	
	7	14	21	28	4	11	18	25	1	8	15	22	29	7	14	21		28
									Dry Run					DBL				
Statistician																		
Lead																		1
Programmer 1																		1
Programmer 2																		0
Programmer 3																		1
Programmer 4																		1
Programmer 5																		1
Programmer 6																		1

**Display 2: Status Meeting Resource Availability**

To Do	Date Added	Completed	Resource	Item	Notes
1	1/4/2016		Lead	Check w ith statistician about deviations	
2					

**Display 3: Status Meeting Action Items**

### COMPLETED PROJECT REVIEW

At the completion of a project, the tracker is useful as a postmortem tool to recap activities and gain insights that can be applied to future projects. Reviewing the Dashboard and the Plan provides a roadmap of what happened to a project from beginning to end. The Dashboard and Other Activities provide documentation for scope changes to explain a late delivery or being over budget. The Validation Log can be used as a teaching tool for the next project; a list of things to watch for that can be addressed at the beginning of the next project.

### CONCLUSION

The process and tools discussed in this paper can help management and entire project team to successfully implement quality, timely and within budget analysis and reporting. It provides ways to set realistic timelines and cost-effective budgets based on clearly defined requirements. It also includes sample tools to effectively allocate, monitor and manage budgets and resources.

The project tracker takes a little bit of time to set up at the beginning of a project, but it is well worth the effort. And while it may take a little time each day for project resources to update it, the amount of time saved trying to figure out if the project is on track or trying to remember what was done more than compensates for the daily task. The project tracker also provides information for status reports to management. It can be used to estimate resources and calculate metrics.

### CONTACT INFORMATION

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