

## Don't Get Lost! A High-efficiency, Low-tech Solution for Navigating Your Department's Many-Many-Many SOPs and Guidance Documents

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### ABSTRACT

In the biotech and pharmaceutical industry, daily activities of biostatisticians and statistical programmers (“we” for short in this paper) are governed by countless processes described in an impressively high stack of documents. From study protocol creation and statistical analysis plan design, through collecting, reviewing, and analyzing patient data, to ultimately producing the clinical study report (CSR), we must continually abide by corporate and functional policies, Standard Operating Procedures (SOPs), how-to manuals, guides, templates, checklists, best practices, and memos in order to remain compliant with regulatory guidance and produce high-quality deliverables in an efficient and timely manner.

Keeping tabs on precisely which of these hundreds of documents to reference in order to perform any task at any time is a daunting proposition by itself. To make matters worse, this sea of documents will likely be relentlessly revised many times, removed, renamed, or added to over the years, adding yet another dimension for us to track.

Companies typically create departmental lists, maps, or trackers to make documents available to staff within our functions. These are generally organized alphabetically by title; numerically by document number; or perhaps by topic. While this goes a long way towards finding content we proactively look for, it does not provide the answer to common questions like, “my database locks 2 months from now; which section in which of these documents should I reference *today* to get ready for that?” Likewise, if we are unaware that we should be looking in a particular document for guidance on the task we’re about to perform, we may unwittingly ignore relevant content altogether. It is also a challenge to ensure everyone stays current with the many updates made to all these documents on an ongoing basis. As a result, teams may be working with outdated guidance; incorrect processes; or inefficient, long-ago improved or even retired best practices, posing risks to functional compliance, quality, and efficiency.

### THE SUPER-SIMPLE, SUPER-EASY SOLUTION

To remediate these challenges, a few years ago we created the Statistical Project Plan (SPP). Rather than organizing content by topic or title as described above, the SPP is organized along a typical study execution timeline. It’s been implemented as a single, easy-to-maintain, department-level, interactive, extensible, checklist-style Excel file that helps each of our study teams navigate this treacherous operational odyssey that starts with product, study and analysis set-up and moves through development, output delivery, completion of documentation and metadata, and study close-out. It comes fully loaded with the following features:

#### **Clarifies the Steps to Take at Each Stage of the Analysis Project**

The SPP provides individual study programming and biostats teams with consistent and specific steps to evaluate at each stage of the analysis development and production process. Each step is based on departmental SOPs, manuals, best practices and guidance documents and includes recommended timing relative to standard milestones such as database setup, snapshot or lock, and CSR completion. Because the file is organized by time rather than by topic, by briefly referencing the SPP for a few minutes once a week, we see exactly which documents and sections therein are relevant to our immediate task at hand so we can remain compliant, efficient, and always up-to-date with current guidance and best practices without having to keep it all in our brain’s RAM.

## Links Documents, Templates, Examples, SMEs, and Other References to Each Step

Each step in the SPP only includes a brief description of a specific activity occurring at a specific point in time during study conduct. It does not repeat detailed information in SOPs, templates, forms or utilities that are relevant to the timeframe at which a step operates; instead, each step has direct hyperlinks into these documents and sections within them if applicable. We further name a subject matter expert (SME) for each step where people can go to ask deeper questions as needed. This way, each analysis development step is linked only and precisely to the right document(s) at the right time with the right “phone-a-friend,” while filtering out all noise from the rest of the library.

## Is Scalable to Easily Allow Ongoing Updates and Additions

Evolving best practices continuously affect existing processes. For instance, changing an existing process may make it more efficient, a process can be identified to become a new best practice or guidance by Amgen or regulators may be revised or extended. To support this highly dynamic environment, the SPP is set up to allow easy addition of new and updated content of existing steps.

In addition, the specific timing of activities is usually intentionally vague in SOPs and other controlled documents. The SPP specifies exact recommended timing for each activity, and we can easily and instantly adjust this timing where needed - for example, based on feedback that it’s more efficient to do something up- or downstream - and let everyone know about this just in time, without having to throw together a whole new training module.

## SHOW ME THE GOODS: WHAT’S IT LOOK LIKE??

As mentioned, the SPP is one Excel workbook that is accessed by several hundred biostats and programming staff. No local copies exist; everyone works in the same single file. This is a must-have feature: since the SPP covers biostats and programming processes end-to-end, updates are frequent and maintaining multiple copies is not feasible. To minimize lock-outs, the file is configured to open as read-only by default; to edit it, users must deliberately make it editable after opening. This setup has so far worked pretty well for our large-scale usage.

The workbook has several sheets as shown in Display 1; in the interest of time, we will primarily focus on the *Study* sheet in this discussion and only touch lightly on the others. Note: this article uses a scaled-down SPP with dummy study numbers and tasks for illustration purposes only; the true SPP is significantly larger and customized for our company.

SPP #	Seq #	Responsibility	Description	Recommended Timing	Documentation or Example	Study/Analysis
			1. Study Document Preparation			Cardio   Drug 444 Study 03 Primary Analysis
			2. Administration, Document Review, and Kick-off Meetings			Cardio   Drug 444 Study 03 Primary Analysis
			3. Set up Annotated CRF and Input Data Sources			Cardio   Drug 444 Study 03 Primary Analysis
			4. Set up Analysis Specifications, Communication, and Tracking			Cardio   Drug 444 Study 03 Primary Analysis
			5. Analysis Development			Cardio   Drug 444 Study 03 Primary Analysis
			6. Prepare for DB Lock			Cardio   Drug 444 Study 03 Primary Analysis
			7. Day of DB Lock			Cardio   Drug 444 Study 03 Primary Analysis
			8. No Later Than Day 1 After DB Lock			Cardio   Drug 444 Study 03 Primary Analysis
			9. No Later Than Day 2 After DB Lock			Cardio   Drug 444 Study 03 Primary Analysis
			10. Day 3 and Later After DB Lock			Cardio   Drug 444 Study 03 Primary Analysis

Display 1. Opening View of the SPP

Not too bad, right? The opening view fits on one screen and reads like a table of contents (TOC) with 4 bulleted major sections and 10 numbered subsections. Looking more closely, one will notice this TOC is organized as a timeline, beginning with study start-up, cruising through analysis development and database lock to ultimately arrive at analysis delivery and close-out. For ease of navigation, we used Excel “grouping and outlining” functionality to show and hide content within each subsection. By clicking on the “+” sign on the far left right below each subsection, Excel will show its content. For example, to see all content covered in Section 1 (Study Document Preparation), we can select the “+” to the left of row 12 which expands that first section as shown in Display 2:

SPP	Seq	Responsibility	Description	Recommended Timing	Documentation or Example	Cardio Drug 444 Study 03 Primary Analysis
<b>Study Start-up</b>						
<b>1. Study Document Preparation</b>						
4562	1.01	Study LP, Biostat	Project management: Identify key crossfunctional study contacts Identify crossfunctional customers in the SPP Study Info sheet so all programmers and statisticians can find these easily	At protocol approval		c3po 19-Jun-15: Done
3151	1.02	Study LP	Project management: Review SOP on reducing time in meetings We pride ourselves on high productivity with only minimal time spent in meetings. Review the linked SOP and prepare your meeting room each time by: <ul style="list-style-type: none"> <li>Turning down the temperature to 58 degrees</li> <li>Ensuring only cold, watery coffee from the day before is available in the room</li> <li>Arranging people to open and close the door starting 10 minutes before mtg ends</li> <li>Hanging scary clown posters on each wall, if not already present</li> </ul>	At protocol approval	SQP 63a (optimize meetings) BP 005 (catering), Section 4, 3 BP 011 (printing clown posters)	c3po 19-Jun-15: Done
6358	1.03	Biostat	SAP: Draft the statistical analysis plan	Starting 4 weeks after protocol approval	SDP 11a (SAPs)	hsolo 26-Jan-16: N/A
3167	1.04	Study LP	SAP: Conduct programming review When reviewing the SAP as part of team review, points to consider: <ul style="list-style-type: none"> <li>Ensure clarity for programming purposes of definitions, analysis sets, derivations, imputations, and analysis methods. Clarify if anything is unclear</li> <li>Review timing of planned analyses and adjust resource estimates if needed</li> </ul>	8 weeks after protocol approval	SDP 11a (SAPs), section 4	c3po 22-Jun-15: N/A
3862	1.05	Study LP, Biostat	SAP: Discuss analysis requirements with Supporting Stat If the Study LP deems it helpful, s/he may arrange an informal SAP overview meeting with the Supporting Stat to discuss [more guidance here]	After SAP approval and before programming starts		c3po 22-Jun-15: Done hsolo 26-Jan-16: Done
<b>2. Administration, Document Review, and Kick-off Meetings</b>						
<b>3. Set up Annotated CRF and Input Data Sources</b>						
<b>4. Set up Analysis Specifications, Communication, and Tracking</b>						
<b>Study Conduct and Analysis Development</b>						
<b>5. Analysis Development</b>						

**Display 2. View of SPP With Section 1 Expanded to Show Content**

Clicking on the “-“ next to row 12 will roll that content back up and the TOC re-appears as before. Any other sections can be expanded and collapsed in a similar way. Further, to expand all subsections at once, click the small “1” at top left; to roll it all back up, click the “2.” While our dummy file only has 80 or so rows, the real file has 250 – which would be mighty intimidating to users without such expand-collapse functionality!

Let’s take a closer look at the content presented on each row in this file by putting row 7 in the screenshot above, under the looking glass. Display 3 shows a magnified version of columns A through H:

File		Home	Insert	Page Layout	Formulas	Data	Review	View	
1	2	A	B	E	F			G	H
1	SPP #	Seq #	Responsibility	Description	Click to Select Product, Study, or Analysis			Recommended Timing	Documentation or Example
3	9151	1.02	Study LP	<p>Project management: Review SOP on reducing time in meetings</p> <p>We pride ourselves on high productivity with only minimal time spent in meetings. Review the linked SOP and prepare your meeting room each time by:</p> <ul style="list-style-type: none"> <li>Turning down the temperature to 58 degrees</li> <li>Ensuring only cold, watery coffee from the day before is available in the room</li> <li>Arranging people to open and close the door starting 10 minutes before mtg ends</li> <li>Hanging scary clown posters on each wall, if not already present</li> </ul>				At protocol approval	<a href="#">SOP 69a (optimize meetings)</a> <a href="#">BP 005 (catering), Section 4.3</a> <a href="#">BP 011 (printing clown posters)</a>
7									

**Display 3. Detailed View of SPP Content for 1 Row as an Example**

In the center, you see a description of something we need someone to do. Specifically, we want someone to review our SOP on reducing time spent in meetings so that more time can be spent actually getting things done. It mentions an SOP that's linked somewhere and then lists out a few key points on how to reduce people's appetite for attending meetings in favor of more targeted offline discussions. This can be labeled the "what."

To reference this item in written correspondence or documents, column A gives an "SPP number," an immutable random 4-digit identifier that is permanently associated with this description. Here, that SPP number is 9151. To facilitate references to an item in meetings, during SPP-based training, or other more fleeting communications, we additionally assign each item a "sequence number" in column B, which identifies the subsection as well as the ordinal position of the item within it, so an audience can find it right away. In this example, the seq number is 1.02, which means this row represents the second item within subsection 1. In contrast to the SPP number, the seq number is not immutable, because if an item prior to this one is added or removed, the seq number will change to 1.03 or 1.01 as well (an automated process as described further below). Therefore a seq number is never to be used in written correspondence or documentation.

To the left, in column E, we see that this is a task to be performed by the study lead programmer (LP). So now we know "who does what."

Moving to the right, in column G, we see a timing factor: it is recommended that the study LP reviews this material very early in the study set-up process, around the time of protocol approval, so as to get maximum benefit from reducing time spent in meetings over the life of the study. We're getting a clearer picture of who does what and when.

Still, this is only a very high-level description of what the study LP needs to do or be aware of at this time. Because our file covers everything from study startup through close-out, we cannot just copy entire SOPs and other guidance docs into the SPP, as it would become mighty overwhelming (not to mention impossible to maintain). The LP may not know where to find yesterday's coffee, nor how to print poster-sized pictures, and there may also be many other things s/he can do to further reduce meeting frequency and duration. All these details are written up in SOP 69a about meeting optimization; Section 4.3 in Best Practice document 005 about onsite catering; and in Best Practice 011 about printing posters.

Column H identifies these documents and even provides a hyperlink to open them. Now we know not only who does what and when, but also where to find more information about this, and we can open these documents directly from our SPP right there. We're saved! Well... were it not for one little snafu. Excel only allows 1 hyperlink per cell, however here we have 3 documents to link in the same cell. To work around this situation, we settled on a relatively simple solution: clicking the *Documentation or Example* column takes the user to the proper section in the *Doc\_Links* sheet right next to the *Study* sheet, which looks like Display 4:

File							Home		Insert		Page Layout		Formulas		Data		Review		View	
		A	B	C	E					F										
1		Sheet	SPP	Seq	Document Link					Notes or Specific Sections Within Doc										
2		Study	9151	1.02	<a href="#">SOP 69a (optimize meetings)</a>															
3		Study	9151	1.02	<a href="#">BP 005 (catering)</a>					Section 4.3										
4		Study	9151	1.02	<a href="#">BP 011 (downloading, printing, and hanging clown posters)</a>															
5		Study	6358	1.03	<a href="#">SOP 11a (SAPs)</a>															
6		Study	3167	1.04	<a href="#">SOP 11a (SAPs)</a>					Section 4										
7		Study	2675	2.02	<a href="#">DOC 111b (directory structures)</a>															
8		Study	2675	2.02	<a href="#">DOC 111b (directory structures)</a>															

#### Display 4. A Solution for Multiple Document Links for One SPP Row

Here, we see the immutable SPP number associated with the item on the *Study* sheet (9151); its corresponding sequence number (1.02); and a hyperlink to the actual document. Because there were 3 documents linked in our example item, here we see 3 rows, each with 1 link. Clicking these will directly open the document. Notice how when we clicked on the linked docs in the *Study* sheet, the cursor went straight to cell B2 on this *Doc\_Links* sheet; that's the first row for this SPP item. The *Doc\_Links* sheet will always open at exactly the right item based on the SPP number of the *Study* sheet row that was clicked. And, clicking the SPP number in column B of the *Doc\_Links* sheet will take you right back to that same row in the *Study* sheet. No searching or scrolling needed any time, no matter where you are in the sheet!

If after reviewing those documents our study LP is still somewhat confused or has questions, column D (not shown here to save space) provides the login ID of the local Subject Matter Expert (SME) for this item. In this case, it's our Administrative Assistant who's a real pro at creating just the right unpleasant and unnerving meeting environment.

So far, our discussion has focused on only 1 item or step in the SPP, but of course, there are many many more. Each is structured along these same lines. If we scroll through the entire SPP *Study* sheet from top to bottom, we basically scroll through all steps in the chronological order in which they should occur to ensure a successful, high quality delivery of your full study analysis project, along with who should do these and where you can find more detailed documentation at that point in time. For example, Display 5 shows the *preparing for database lock* section around halfway down our dummy SPP:

File									
		Home	Insert	Page Layout	Formulas	Data	Review	View	
1	2	A	B	E	F			G	
1	2	SPP #	Seq #	Responsibility	Description	Click to Select Product, Study, or Analysis		Recommended Timing	Do
3									
58	9815	6.12	Study LP	Blinded data: Apply restricted access control group Elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim			1-2 days before initial DB lock	DOC	
59	8977	6.13	Study LP	Adjudication: Ensure adjudicated reviews (manual look-up tables) are done Ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim			1 day to DB lock		
60	4404	6.14	Study LP	Avoid accidental overwrites: Stop any automated ADaM and TFL runs Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis			1 day to DB lock		
61									
62	Database Snapshot or Lock								
63	7. Day of DB Lock								
69	8. No Later Than Day 1 After DB Lock								
75	9. No Later Than Day 2 After DB Lock								
81	Analysis Delivery and Close-out								
82	10. Day 3 and Later After DB Lock								

**Display 5. Showing How SPP Steps Progress in Time As We Scroll Down**

Notice that while our sample item discussion focused on study start-up activities, now we're looking at steps to be taken much further along on a study timeline – right up to database lock.

Lead statisticians and programmers are asked to check the *Study* sheet every few weeks for just 5 minutes, to review briefly which activities should have typically occurred over the past few weeks and which activities are coming up for them in the few weeks ahead. With each item, they will also get a just-in-time reminder to review applicable SOPs and other guidance documents, or even specific sections therein, to get these tasks done. This removes the need to keep this vast library of controlled documents in our brain's RAM at all times, keeps up compliance, and greatly reduces the chances that some necessary step or another is accidentally missed or done at a less-than-optimal time. As a bonus, it also helps coordinate activities between statisticians and programmers by reminding them what hand-offs to expect over the upcoming few weeks.

In this article, we referenced a small, dummy SPP purely for illustration purposes. Our real SPP is *much* more comprehensive and extensive. Of course, expanding all rows in such a true SPP would fill up many screens and make it hard to see the overall flow of steps, responsibilities, hand-offs, and timing. To facilitate a more at-a-glance overview of the entire analysis development and delivery process, we added a *Study Outline* sheet which is automatically generated and refreshed by reading key information from the *Study* sheet. The *Study Outline* sheet is for reference and overview purposes only and would not be used to get detailed info on each step as shown in Display 6:

A	B	E	F	G
SPP #	Seq #	Responsibility	Description	Recommended Timing
2			Click to Refresh Study Outline (do NOT edit manually!)	
<b>Study Start-up</b>				
<b>1. Study Document Preparation</b>				
6	4562 1.01	Study LP, Biostat	Project management: Identify key crossfunctional study contacts	At protocol approval
7	3151 1.02	Study LP	Project management: Review SOP on reducing time in meetings	At protocol approval
8	6358 1.03	Biostat	SAP: Draft the statistical analysis plan	Starting 4 weeks after protoc
9	3167 1.04	Study LP	SAP: Conduct programming review	8 weeks after protocol appro
10	3862 1.05	Study LP, Biostat	SAP: Discuss analysis requirements with Supporting Stat	After SAP approval and before
<b>2. Administration, Document Review, and Kick-off Meetings</b>				
13	3334 2.01	Biostat	Project planning: Plan for data transfers, analysis, and reporting	Hold meeting no later than a m
14	2675 2.02	Study LP	Project management: Set up study and/or analysis directory	Before work on the analysis t
15	5125 2.03	Study LP, Biostat	Database: Review draft case report form (CRF)	8 weeks after protocol appro
16	8273 2.04	Biostat	DMC: Finalize Data Monitoring Committee charter after kick-off meeting	Before first subject enrolled
<b>3. Set up Annotated CRF and Input Data Sources</b>				
<b>4. Set up Analysis Specifications, Communication, and Tracking</b>				
<b>Study Conduct and Analysis Development</b>				
<b>5. Analysis Development</b>				
36	4048 5.01	Biostat, Study LP	Respond to questions about specs and content of ADaMs and TFLs	Start during ADaM developme
37	8539 5.02	Study LP	ADaM: Run Pinnacle 21 (OpenCDISC) Checks	Once draft ADaMs available
38	6193 5.03	Study LP	MedDRA, WHO Drug: Check the version upgrade schedule	6 months to DB lock
39	5534 5.04	Study LP	Blinded studies: Set up (dummy) treatment listing	No later than 3 months to DB l
40	2042 5.05	Study LP	PI: Check titles and footnotes against the Amgen Style Manual and Reg Pub needs	Around 3 months before DB l
41	2413 5.06	Biostat	TFLs: Conduct draft TFL review (output review)	Complete 12 weeks before D
42	5473 5.07	Study LP	FDAAA: Create draft XML file for ClinicalTrials.gov	Complete 10 weeks before D
43	3877 5.08	Study LP	EudraCT: Create draft XML file for EudraCT posting	Complete 10 weeks before th
44	4643 5.09	Study LP	SDTM: Evaluate SDTM and related DES compliance report findings	8 - 12 weeks to DB lock
<b>6. Prepare for DB Lock</b>				
47	4443 6.01	Study LP, Biostat	Lessons learned: Populate lessons learned (LL) tracker	2 months to DB lock
48	6495 6.02	Study LP	Project management: Confirm team schedule and identify back-ups	2 months to DB lock

Display 6. A Quick Overview: The Study Project Outline Sheet

## GREAT, IT'S A SUPERCHARGED CHECKLIST. NOW HOW DO YOU GET PEOPLE TO ACTUALLY USE IT?

Fair question! Most organizations have their fair share of checklists floating around, and if we were to simply toss our SPP over the fence and duck for cover, it would likely be received with a grunt and a shrug as yet another checklist to distract people from their day jobs, which in turn would quickly relegate our masterpiece to the realm of irrelevance where no one would reap the vast benefits of having all this comprehensive, just-in-time information right at their fingertips.

To counter that, we added an interactive feature to what might otherwise have been a dusty checklist by providing one individualized column for each active analysis project to the right of the *Documentation* column as per Display 7:

	F	H	I	J
	Description	Documentation or Example	Cardio   Drug 444 Study 03 Primary Analysis	Onc   Drug 071 Study 99 Interim Analysis
rt-up	Click to Select Product, Study, or Analysis			
Document Preparation				
	<b>Project management: Review SOP on reducing time in meetings</b> We pride ourselves on high productivity with only minimal time spent in meetings. Review the linked SOP and prepare your meeting room each time by: <ul style="list-style-type: none"> <li>Turning down the temperature to 58 degrees</li> <li>Ensuring only cold, watery coffee from the day before is available in the room</li> <li>Arranging people to open and close the door starting 10 minutes before mtg ends</li> <li>Hanging scary clown posters on each wall, if not already present</li> </ul>	<a href="#">SOP 69a (optimize meetings)</a> <a href="#">BP 005 (catering), Section 4.3</a> <a href="#">BP 011 (printing clown posters)</a>	c3po 19-Jun-15: Done	yoda 17-Feb-2016: Done [evil laugh]
	SAP: Draft the statistical analysis plan	<a href="#">SOP 11a (SAPs)</a>	hsolo 26-Jan-16: N/a, no SAP needed	
	<b>SAP: Conduct programming review</b> When reviewing the SAP as part of team review, points to consider: <ul style="list-style-type: none"> <li>Ensure clarity for programming purposes of definitions, analysis sets, derivations, imputations, and analysis methods. Clarify if anything is unclear</li> <li>Review timing of planned analyses and adjust resource estimates if needed</li> </ul>	<a href="#">SOP 11a (SAPs), section 4</a>	c3po 29-Jan-16: N/a, study has no SAP	yoda 19-May-2016: Done

### Display 7. The Interactive Component to the SPP: Individual Analysis Columns

In Display 7, column J provides a column dedicated to an interim analysis on study 99 for oncology drug 071. When the person responsible for an item completes it, they add a disposition here so they know that step has been completed and they can “check it off.” Entries in this column are to be made in the format of *login-id dd-Mon-yy: disposition*, where *login-id* is the user’s network login; *dd-Mon-yy* is the date of entering the disposition info in this cell, and *disposition* is the indicator of whether the step was done (completed), not applicable, or perhaps still in progress. Structuring entries in this format allows instant automated data entry checks to verify completeness.

For example, study 99 lead programmer Yoda indicated on 17-Feb-2016 that he completed the review of the 3 documents linked in column H for the activity described in column F. A few months later, when the SAP was made available by the statistician, he also conducted the programming review thereof as acknowledged in the last row shown.

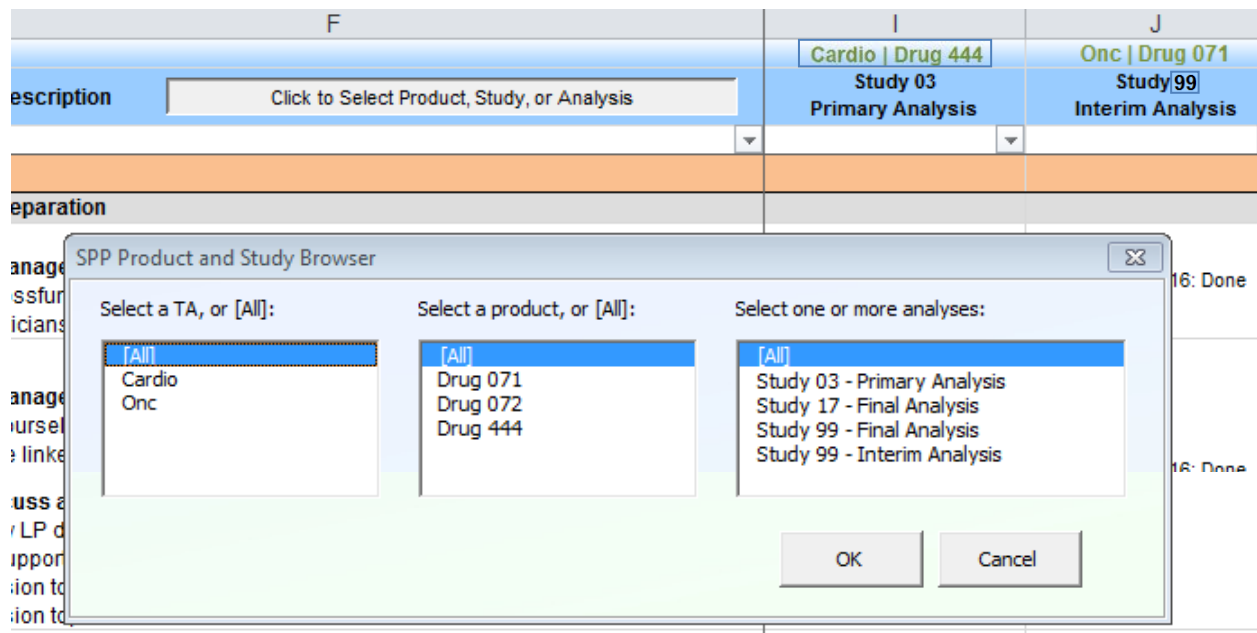
Likewise, on study 03 for Cardiovascular drug 444 shown in column I, lead programmer C-3po and statistician Han Solo dispositioned each item assigned to them. Notice how Mr. Solo described on 26-Jan that no SAP was needed for this specific analysis and consequently C-3po indicated 3 days later that for that reason he did not conduct a SAP programming review. Using N/a with a brief explanation is a great practice to ensure no items are accidentally forgotten; case in point, in column J the statistician did not provide a disposition for writing the SAP, so does that mean no SAP was needed; or that this wasn’t done; or that the statistician simply forgot to fill this out? Since Yoda reviewed an SAP on 19-May, we can argue the latter, but in many other cases leaving a cell blank only raises ambiguity. Periodic review of the SPP can help fill in these blanks and remove the ambiguity.

Leads are encouraged to spend 5 minutes every few weeks to sign off in this way on any items completed during the past few weeks and remind themselves of steps coming up over the next few weeks. This also provides an excellent at-a-glance visual of any potential compliance gaps on an analysis project: for example, if a study is locking 1 month from today, then for all SPP items with a recommended timing up to that point we would expect to see a disposition in the column for that project; any blank cells up to that point may present a step that was overlooked.

As a final point to make on this, of course in a company that runs hundreds of trials a year, one would quickly see an equal number of project columns in the SPP. To enable people to navigate instantly to their own study column, we provide a project navigator that pops up when clicking the gray “Select Product, Study, or Analysis” column at the top of column F; here, people can instantly select one or more analyses, studies, or projects within or across therapeutic areas (TAs) as shown in Display 8, such that



selecting a TA subsets the center box to only the products within that TA, and likewise selecting one or more products in the center box subsets the studies and analyses to only those within these products:



**Display 8. One-click Navigation to Your Own Project Column!**

If the user selects “study 99 – Interim Analysis” in the right-most list box and then “OK,” the SPP will only show the project column for that analysis and automatically hide from view all other project columns. It’s almost like having your own SPP all to yourself!

## THE MAGIC BEHIND THE SCREEN: VISUAL BASIC FOR APPLICATIONS

Maintaining something as broad as the SPP with all its internal and external links and dependencies can be a daunting task without some solid automation running behind it. We deployed Visual Basic for Applications code behind the scenes which provides or automates the following:

- Navigation tools
- Closing sections back to the TOC when the file is saved and closed
- Checking data entry of new text in study columns (explained below)
- Displaying the status of your specific study and analysis (also explained below)
- Creating hyperlinks between SPP worksheets (e.g., between *Study* and *Doc\_Links* sheets)
- Assigning unique random SPP numbers to new items
- Renumbering sequence numbers after SPP items (steps or rows) are deleted or added

## HOW IS THE SPP USED AND MAINTAINED?

### SPP Coordinators

The SPP is maintained as a part-time sideshow by two volunteer staff members from the programming team who for their efforts are awarded the dubious title of “SPP Coordinators”. Such staff are preferably located in different time zones to provide maximum support across the global organization.

Coordinators add new analysis columns where study teams can track their progress; help teams troubleshoot technical issues with the file; and add or revise descriptions, timing, and links for steps in response to departmental document or process changes to ensure the SPP is always up to date. In addition, based on lessons learned from individual study teams, Coordinators can modify steps or even add guidance not documented elsewhere, in order to give voice to the silently understood general knowledge that often hamstrings new team members.

Because the SPP itself only reflects controlled documents that exist outside of it and does not make or define compliance-related content by itself, no formal approval is needed to make revisions in the SPP and such updates can often be made the same day. The review process typically consists of a quick sense-check by Coordinators and requestors via e-mail or a quick IM, after which the new content is immediately released into production for instant consumption by teams who arrive at new or updated content depending on the timing of upcoming milestones in their analysis project.

**This lean, practical approach ensures SPP content is always “live and hot,” reflecting the latest and greatest without the hassle of dealing with extensive update procedures and approvals!**

### Lead Programmers and Biostatisticians

As we already discussed, leads periodically indicate dispositions in their analysis columns around how steps were addressed or if they were deemed not applicable. They also reach out to SPP coordinators to add or change steps based on lessons learned.

### Controlled Document Authors

When documents that impact Biostatistics and Programming are revised, retired, or newly rolled out, one or more steps in the SPP will likely also need to be revised, retired, or added. SPP Coordinators typically ask document authors to review the SPP and advise on such revisions which are subsequently made by the Coordinators. Because of the low administrative overhead inherent to the SPP implementation, such updates are usually made within a few days from start to finish, so that the SPP always remains in lock-step with the vast document library.

## CONCLUSION

The SPP has been in use at our organization for a number of years now and is recognized as a key tool in keeping biostatistical and programming teams aligned on the ever-changing requirements, processes, tools, and best practices to be applied during the conduct of any routine clinical trial analysis project. It has successfully been kept up to date against hundreds of continually updating internal and external documents and guidelines by a very small group of individuals with a relatively insignificant amount of effort, which in turn provided study teams with all required information right at their fingertips in a just-in-time manner.

Organizations may periodically create new roles in their organization or recognize that existing roles can benefit from having their activities and handoffs more visible. Even after the SPP went into production, it was very easy for us to integrate clearly defined responsibilities of such new roles into the SPP to show

not only what these other roles or groups do along the path of analysis development, but also where the hand-offs are between them and the other functions like Biostatistics or Programming.

Going beyond the immediate analysis work, this tool has also demonstrated value as a training framework for any new hires in both biostats and programming; clarifying and revising functional staff role descriptions and responsibilities; and process mapping and revision in cross-functional efficiency initiatives.

Given the high yield in functional benefits coupled with the minimal effort required in setup and maintenance, we feel a tool like this can certainly add tremendous value to your organization as well!

## CONTACT INFORMATION

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