

## Woops, I Didn't Know! An Elegant Solution to Let Your Entire Department Benefit from Individual Lessons Learned

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### ABSTRACT

After completing a clinical trial analysis, individual programming and biostatistics teams often produce lessons learned (LLs) based on the project they just finished. Such LLs are typically captured in slide decks or Word files, shared once as a presentation within the small team, and then stored in the individual study directory to soon be forgotten about.

As many LLs may actually apply to the entire department, the result is a treasure trove of wisdom lost:

- After a while, the audience won't remember these lessons or where to find them
- New hires into the team may not know these lessons were ever presented
- People in other product teams may not know an issue was already seen before
- People in other functions may not know they can improve processes that impact stats and programming

If such LLs don't translate to concrete, written changes to the departmental SOPs and manuals routinely referenced by all staff, then not only will the same mistakes be made all over again, but also what worked well will not be generalized.

We will show how we successfully fixed this broken cycle via a small lean departmental Continuous Process Improvement group which proactively seeks LLs from individual teams after completing each study report. The group then works hand in hand with each team to translate those into updates to departmental guidance documents such as SOPs, manuals, checklists, and templates. This way, staff in the entire department immediately benefits from the LLs encountered in any one study team!

### INTRODUCTION

Following the completion of a clinical trial analysis, individual programming and biostatistics teams often produce lessons learned (LL) that reflect specific challenges encountered during the development, QC, and delivery of the analysis project. Taking a moment of pause to reflect on a project we just finished is undisputedly an excellent idea. However, the traditional way in which these LLs are often collected and presented may realize only a fraction of their full potential impact on the organization as a whole as discussed below:



### Some Teams May Not Produce Lessons Learned at All

If left to their own devices, some teams may be more interested in capturing and presenting their LLs than others. As a result, valuable LLs encountered in a team that doesn't capture and share them will not see the light of day for their team members, let alone for the wider product and department. In turn, whatever issues this team encountered will likely re-occur elsewhere in the future, and any innovations they came

up with will not be generalized to other teams who will continue to operate less efficiently or spend lots of effort developing their own solutions in the same area.

### **Other Functions May Remain Blissfully Unaware of Things They Could Do Better**

In our experience, perhaps because of our analytical disposition, programming and biostatistics teams are often the most proactive in driving the development and presentation of LLs on trial analysis projects they just delivered. However, many of the LLs encountered on these analyses have touchpoints beyond programming and biostatistics and involve processes in other functions such as Data Management, Clinical, Safety, Regulatory, or Supply Chain Management. Inefficiencies in operations or deliverables in those functions may cause significant grief in downstream consumers such as programming and biostatistics. Unfortunately, often such LLs are only presented within our own function and not shared with the other groups who actually own the root cause of such issues. As a result, the challenge will likely arise again in the future.

### **Our Functional Colleagues May Also Stay Unaware**

Once a study team has compiled their LLs, they often present them one time in a small meeting within their own study, indication, or - at most - product team. Colleagues working on other studies, indications, and products do not attend those meetings and hence will not share in the resulting enlightenment. It is therefore likely that if the same circumstances were to come to pass in their projects, the same problem will rear its head again.

### **Lessons Learned Are Quickly Forgotten and Lost**

Historically, LLs are captured in slide decks, spreadsheets, or word-processing files which are saved in the study team folder on a functional server. After a few months, anyone who worked on the study or saw the particular LL presentation would likely forget where in the maze of the departmental directory tree the LL files for this study are stored – and in the even longer run, they may forget these LLs were ever generated to begin with.

This compartmentalized approach of saving and preserving LLs only within the project area for which they were generated also further contributes to the problem described above where our functional colleagues remain clueless about the LLs we encountered in our own study. Even if our colleagues heard about our LLs, they would have no clue where to find them within our product-specific folder tree - and even if they had an educated guess, they may not have access! Likewise, staff new to the compound or to the company would not know about these historical LL files and hence would likely fall into the same inefficiencies again if similar situations were to arise on their projects in the future.

### **Root Cause Analyses Aren't Always Done (or Done Right)**

The primary reason behind identifying a LL is to prevent the problem from reoccurring in the future. In order to definitively accomplish this, the root cause underlying the problem described in the LL needs to be addressed. We've seen teams simply presenting their observation of what went wrong without identifying the true underlying issue; or identifying an incorrect root cause for it; or hopping down the right bunny trail towards the true root cause but stopping a few layers short of actually getting to the true root cause.

Rather than addressing the underlying disease itself, such "solutions" only fight superficial symptoms, which sets up the department for a serious game of whack-a-mole where similar issues keep popping up in each "lucky" team.

## **Solutions Aren't Always Identified**

Related to the root-cause problem described above, teams describing and presenting LLs may sometimes also omit the solution they applied to a LL or would recommend. This leaves it up to the audience to come up with their own solution which may not be as optimal as the one already put in place in the original study team. It is then more likely that the audience will forget about this LL altogether as they didn't get a powerful a-ha moment while the LL was being shared with them.

## **Lessons Learned May Only Focus on What Went Wrong, Not on What Went Right**

When sharing opportunities for future improvement, "what worked well" is just as important as "what went wrong." Unfortunately, LLs often focus on the latter and omit the former.

For example, a study programming team may have invented a new utility to make part of their work more efficient, or the biostats and programming team worked together to improve the manual cross-functional adjudication process for certain types of data. Other study and product teams can benefit massively from such positive LLs, frequently even more so than from the traditional did-not-work-well LLs – but if these are not captured in LLs then likely that potential is lost to everyone else. This paragraph uses the PaperBody style.

## **SO... HOW COULD LESSONS LEARNED REALIZE THEIR FULL POTENTIAL?**

The answer is straightforward: flip each of these challenges upside-down, and voilà, there's our ideal state where:

- Biostats and programming teams who completed an interim, primary, or final analysis generate LLs
- Other functions are engaged to update their processes as needed based on these LLs
- Functional colleagues outside our immediate study team can steer clear of issues noted in the LLs
- We ourselves permanently remember to not make these same mistakes again in the future
- Issues described in the LLs can be addressed directly at their root cause
- Solutions are identified as part of each LL
- Everyone gets to benefit from valuable tool or process improvements - or any other innovation

Unfortunately, asking individual study teams to live up to that ideal state presents a huge challenge. Study leads may not have experience with proper root-cause analyses, or they may not have time nor interest in capturing and presenting LLs properly. Thus, LLs might still not be produced and give inadequate root-cause analyses or solutions.

Even if we could get all individual teams sufficiently energized to create LL files after each applicable analysis project, the next question is how to organize all that content and make it available to everyone else. Dumping such LL files to a central location is an improvement over keeping them buried in a vast web of study-level directories, however it is still far from ideal.

For one, it's safe to say no one would be brave (or bored) enough to read through such a growing central library of LL files periodically to keep all these accumulating nuggets of wisdom fresh in their minds. In addition, even if someone in a specific situation vaguely recalls having seen a solution in someone else's LLs, they wouldn't know offhand in which of these dozens or hundreds of LL files in the central area that specific bit of info is hidden.

A much better approach is to relate the root cause for each LL to functional and cross-functional SOPs, manuals, checklists, templates, or any other guidance document and guidance documents, and then revise those documents to reflect an optimized process that would either prevent the LL issue from reoccurring or promote the innovative new tool or process adjustment described in that LL. Since each study team is trained on and must follow these functional documents, this approach solidly and transparently embeds study-level LLs in everyone's day-to-day operations without needing to review (and re-review) tons of separate individual LL files of varying quality and format.

Since this type of approach would require even more determination, persistence, coordination, experience, and judgment than just creating proper LL files to begin with and saving them centrally, it seems clear that a dramatically different, more centrally coordinated approach is needed to truly unlock the full treasure hidden in these study-level LLs. In our programming organization, we chartered this coordinated effort as a "Continuous Process Improvement team," or **CPI** for short.

## **A LOOK UNDER THE HOOD OF OUR CONTINUOUS PROCESS IMPROVEMENT (CPI) TEAM**

### **Who Makes up the CPI Team**

Our CPI team is comprised of half a dozen regular full-time staff from the programming function. The chair and co-chair oversee CPI operations, provide guidance to CPI members on how to tackle tricky LLs, and help identify subject matter experts (SMEs) in other groups or departments for follow-up.

### **How CPI Communicates Internally**

The team meets every two weeks for an hour to discuss pending LLs and to seek suggestions from team members on the best approach to tackle particularly tricky LL items. Outside of these meetings, team members primarily use e-mail to communicate offline.

### **How CPI Communicates with Contributing Study Teams and Dispositions LLs**

While teams are encouraged to use the CPI LL slide template (shown further down in this paper), they can use any format convenient for them, be it Word, Excel, PowerPoint, or even e-mail. When all LLs have been summarized for their project, the study lead sends the file to CPI via e-mail.

Once LLs are received, CPI staff immediately takes the following actions to triage:

- The CPI lead saves the original LL file to our central online location and hyperlinks it into the master LL tracker. No reformatting is done other than renaming it to a standard CPI naming convention.
- The CPI lead notifies all CPI staff that a new LL file is available and asks them for a quick 5-minute review to allow all CPI staff to signal red flags, conflicts with or extensions of other LLs they may already be working on, or suggestions to look at previously dispositioned LLs they worked on before to avoid redundant investigative work.
- The CPI lead then assigns all LLs in the file to 1 CPI member for dispositioning along with a timeline.
- The CPI member determines which LLs apply departmentally or crossfunctionally and proceeds with only those.
- The CPI member works with the originator to identify a proper root cause for each LL noted in the file.
- The CPI member works with the business owners of applicable guidance docs or tools to make the updates and coordinates ongoing input and review by the originating study lead.

- When all LLs in the file have been addressed in this manner, the CPI member closes out the file in the LL master tracker and thanks the study lead for their contribution to continuous improvement.

Key to this setup is that while LLs may be received in various formats, no information is reformatted or transcribed into different places or structures. Instead, CPI staff works directly in the LL file in its originally received format from the study lead. This embodies efficient, lean thinking by reducing waste and unnecessary hand-offs, and also facilitates clarifications and discussions with the contributing study team based on the format they themselves assembled to compile and share their LLs.

### Managing the Lessons Learned Library: Tools and Locations

The CPI team maintains a LL master tracker, an Excel workbook that catalogues the LL files collected from teams as well as information on which functional SOPs or other documents were updated based on each individual LL file. In addition, the tracker hyperlinks to original LL files received in any format - e-mails, Word, Excel, PDF, PowerPoint, etc. Display 1 shows a screenshot, split across 2 lines as there wasn't enough space to display the rows intact:

A	B	C	D	E	F	G	H
TA	PRODUCT	PROTOCOL	ANALYSIS	DBL DATE	Submitted By	CPI Logged Date	CPI Closed Date
INFLAM	AMG 999	20170112	Final	7-Dec-2016	John Smith	3-Jan-2017	13-Jan-2017
ONC	AMG 100	20170106	Final	12-Dec-2016	Mary Jones	3-Jan-2017	10-Jan-2017

I	J	K	L	M	N	O	P
Assigned CPI Member	STATUS	TOTAL LL ITEM	TOTAL LL Pending Disposition	TOTAL LL Process Updates	SPP/SOP/MAN to be Updated (link?)	ISSUES / IMPACT (See Original LL file)	CPI COMMENTS
Sue Williams	Closed	16	0	5	SPP 123; SPP 909; MAN-808; SOP-505; MAN 101 Section 6.4.1.	<a href="#">amg999_20170112_LL.xlsx</a>	F/U with GRB group to update the SOP-101 to include the actual BOXID file (without treatment codes) in the delivery for Biostats.
Peter Johhson	Pending	8	2	1	Lead Programmer Guidance Document Updated	<a href="#">AMG100_20170106_LL.xlsx</a>	

**Display 1. Example Departmental Master Lessons Learned File Tracker**

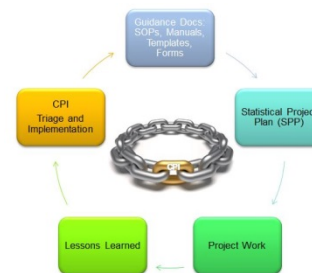
Based on this worksheet, we created a simple pivot table in a second worksheet to summarize the current status of all LLs received in CPI to provide data for metrics we will describe in a later section in this paper.

### REACHING OUT: HOW TO GET LEADS TO CONTRIBUTE LESSONS LEARNED

While most everyone would agree with the concepts outlined above, it's a different story altogether to motivate teams to actually make the time to pull together their LLs once an analysis is completed, let alone send them on to another group who might ask them all kinds of questions about root causes! Thus, our CPI team employed the following nefarious schemes to solicit optimal engagement from study teams:

## Brand the effort: create a logo

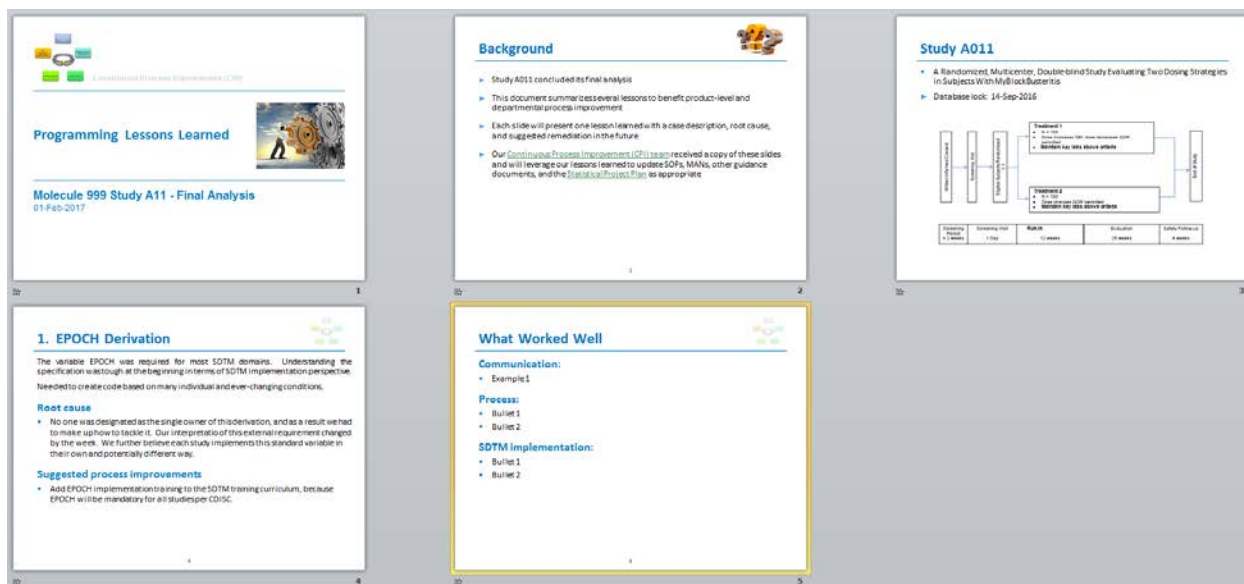
We designed a logo to illustrate the circular nature of a continuous improvement effort like ours, as shown to the right. This logo is used to “brand” materials and presentations developed or shared by our CPI team and also adorns the CPI online portal on our company’s intranet.



Branding our efforts makes CPI materials instantly recognizable to consumers and increases our visibility.

## Provide LL templates

We provided a template to capture LLs in slide deck format which teams can pull down as a starting point to summarize their own lessons learned. Note that the template not only summarizes what didn’t work well and hence could be improved next time, but also any new approaches that worked well for the team that could benefit from being generalized across the entire department as a new or revised best practice. Staff are encouraged to populate their copy of the template with LLs during analysis development on an ongoing basis right as they are observed, rather than only at the end of the analysis project when LLs may often have been forgotten. Display 2 shows an outline of our template:



Display 2. Departmental Lessons Learned Slide Deck Template

## We set up our dedicated online portal

We designed an online portal on the company’s intranet to showcase our CPI efforts. This portal is fully integrated into and accessible from our wider department’s portal, and provides information such as our mission statement; the CPI charter; CPI membership; links to key functional pages outside the CPI portal; links to the LL master tracker and the LL file library; various LL templates; and contact information.

## Reach out to study teams directly every 6 months

Twice a year, the CPI lead or designee will reach out 1-on-1 directly to the product lead programmer on compounds on which at least 1 full-analysis database lock occurred during the past 6 months. This

communication lists out the database locks on this specific compound and asks the lead to confirm when their study teams will compile and send LLs to the CPI team if not done already. We found we received many more LLs contributions this way than if we simply send out periodic mass reminders to all staff at once; people respond better if addressed personally.

### **Pull as much weight in CPI as possible**

Given that our CPI team is entirely comprised of programming staff “with a day job,” the original CPI charter tried to minimize overhead on CPI staff by pushing much of the triaging and dispositioning burden outlined above to the contributing study team. We found that with this light-touch approach, LLs typically would not progress through the dispositioning steps, let alone result in tangible updates to functional guidance that could benefit other study teams in the future. Contributing teams did not know how to approach identifying the root cause or who to work with for corresponding document updates. In addition, it was challenging for document owners or SMEs in other functions to receive requests for updates from multiple study leads on similar topics.

This strategy was therefore reversed to have CPI staff take a much more proactive role, arriving at the triaging and dispositioning process outlined earlier in this paper. This has resulted in a much greater impact via updated departmental guidance and tools; helped develop our CPI staff by increased exposure to many other teams and functions; and encouraged individual study teams to continue to contribute LLs given that their work in triaging and dispositioning is now more fairly balanced between them and CPI.

### **Keep everyone aware via periodic staff meetings**

CPI also has a 10-minute standing item in our departmental all-staff meeting every 2-3 months to provide all programming staff an update on process improvements based on submitted LLs; to thank contributing study teams for sharing these with the department; and to display uptake of LL contributions along with a continued call for team contributions. This is presented by a different CPI member each time and aims to realize the following benefits:

- Give CPI continued visibility to all staff by waving our arms to remind everyone we're still here!
- Energize more teams to share their study-level LLs with CPI
- Motivate CPI members to make process updates before each meeting, to not show up empty-handed
- Make individual CPI members more visible by rotating them through these standing presentations

## **MEASURING SUCCESS: THE IMPACT CPI HAD ACROSS OUR ORGANIZATION**

To measure the health and success of our efforts, we instituted several metrics which can be tracked over time based on the LL master tracker described above. To demonstrate the value of CPI efforts and also measure whether we ourselves are learning to become more efficient in our LL-related work over time as well, we recorded the following:

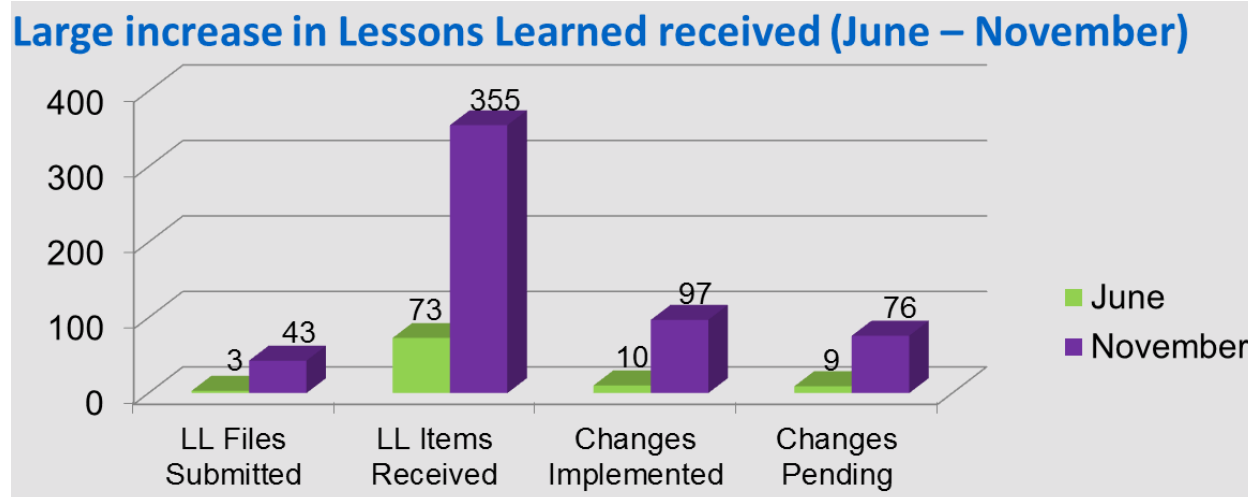
Metric(LL = lesson learned)	Definition
LL files received	Number of files (slide decks, Word files, etc.) containing sets of LLs from a study team sent to CPI
LLs received	Number of individual, actionable lessons learned sent to CPI by study teams
LL-based changes implemented	Number of individual LLs that resulted in tangible updates to controlled documents used by everyone in a department



Metric(LL = lesson learned)	Definition
LL-based changes pending	Number of individual LLs for which CPI staff is working with document owners to make updates to controlled documents used by everyone in a department
CPI LL action speed	Average number of days between LL file received and LL file fully dispositioned (i.e., all LLs inside it were either actioned or closed out as study-specific)

**Table 1. Quantifying Success: CPI Metrics**

A graphic of the first 4 metrics is presented in Display 3, contrasting June 2016 to November that same year (cumulatively). The last metric is still under development and not covered further in this paper.



**Display 3. Quantifying the Impact of CPI Efforts in 2016**

The graphic above tells a story that warrants some explanation to help your organization avoid some pitfalls. The first year or so after the CPI effort was officially chartered, the group relied heavily on the departmental Statistical Project Plan (or SPP – a step-by-step checklist reminding biostatistics and programming staff about who should do what and when at any point in the analysis process; this is described in much more detail in PharmaSUG 2017 paper, BB16) to encourage study leads to compile and submit their lessons learned. The group also gave a one-time presentation about its goals and objectives when it kicked off in mid-2015 to encourage team engagement. This somewhat passive wait-and-see approach did not yield significant input from study teams: out of over a hundred active study analyses, only 3 teams sent CPI a file with LLs during that first year, for a total contribution of 73 individual LLs.

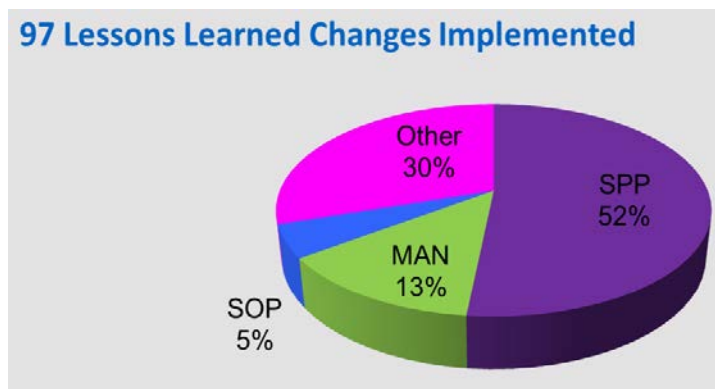
Based on this initial metrics read-out, the CPI team switched to a much more proactive strategy. First, we inventoried our corporate milestone tracking system to determine which study teams had an interim, primary, secondary, or final analysis database lock between CPI roll-out in mid-2015 through June 2016. These types of “full” analyses are typically quite involved, in contrast to analyses like publications or annual reports which are often much quicker and less likely to generate LLs. Next, one of the CPI team members sent a 1-on-1 e-mail directly to each individual product lead programmer for compounds on which at least 1 such database lock had occurred during this time. The e-mail briefly re-introduced CPI, listed out all studies and database locks identified by CPI on this specific compound, and asked the leads to confirm when their study teams could compile and send lessons learned to the CPI team. This direct-to-consumer approach worked miracles, as people were much more responsive after being addressed



directly rather than in a mass group communication, resulting in a significant uptick in LLs contributed by November.

It's worth mentioning that as shown in the graphic, not all LLs contributed by teams are successfully translated to updates in departmental documents or tools. In fact, only 97 updates were made based on 355 LLs submitted, which one could interpret as a 25% yield. There are a few reasons for that. For one, many LLs are in fact study-specific and not readily generalized to departmental improvement, hence CPI will not pursue those beyond the initial triage. For another, updates to controlled documents often have significant review and approval overhead, which may delay their implementation. And sometimes it's just down to a team's not following the correct existing procedure!

Looking more closely at the 97 changes made in various documents by November, Display 4 shows that most of these were made directly in our SPP (see PharmaSUG paper BB16); only a small portion in SOPs, which is understandable given that SOPs are usually more high-level while LLs often deal with detailed operational improvements; and the remainder in various manuals (13%), utilities, web portals, templates, and reports (30%). Note that without our CPI framework in place, all these LLs would likely have been lost!



Display 4. Document Updates Based on LLs

## CONCLUSION

For many years, study-level lessons learned were not routinely elevated to changes in departmental guidance documents and tools routinely used by all staff. As a result, the same mistakes were made over and over again, and things that worked well in one team were not generalized to others.

By chartering a Continuous Process Improvement team within our function, we successfully fixed this broken cycle. This group of functional SMEs proactively seeks LLs from individual teams after each analysis project, and works hand in hand with each team to translate those into updates to departmental guidance documents and tools. This has been a fantastic boost on our ongoing quest to continually improve ourselves and our department!

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## CONTACT INFORMATION

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