The Discussion portion of the Lessons Learned (LL) Tool will help you to direct a focused discussion based on the answers from the LL Questionnaire. The purpose of this tool is to encourage a frank discussion surrounding the life cycle of a study from activation to completion. This knowledge can be applied to strengthen future recruitment efforts and overall study performance.

# Part 1: Clinical Trial Information

**Record the following information for the discussion:**

**Date:** **Date of discussion – This must be between accrual closure and up to 2 years post closure**

**Attendees:** **List attendee names – This should be everyone who was sent a questionnaire**

**Absentees:** **List any absentee names**

**RE: Lessons Learned Discussion for** **Trial name**

# Part 2: Open Discussion Questions

**Create a list of appropriate questions based on the questionnaire responses. If “neither agree nor disagree” was selected on the questionnaire for any statements, ask why a neutral response was given and try to elicit a response for discussion. If “not applicable” was selected, consider whether or not the response is valid based on that person’s role; if this is not an appropriate response, ask why this response was selected and follow-up with the negative/positive discussion questions.**

**Evaluation of clinical trial portfolio**

| **LL Questionnaire Statements** | **Related Open Discussion Questions** | |
| --- | --- | --- |
| **Negative LL Questionnaire Response** | **Positive LL Questionnaire Response** |
| This trial made a significant contribution to the disease site team's and/or institution's research portfolio. | If no, why not?  What might be the cause? (for example: resource or capacity issues resulting in inability to recruit, patient population lacking, unsuccessful/negative study, etc) | If yes, what was the impact this study has made?  In what ways did this trial contribute to the disease site team or institution’s research portfolio? (for example: recognition, authorship, change in practice, etc) |
| Given the opportunity, I would select such a trial again for my/my team's research portfolio. | Why not?  What are the reasons for avoiding future studies such as this one?  What does this tell you about your team and/or our site weaknesses? Is it possible to address these weaknesses? How might we do this? | Why?  What does this tell you about your team and/or our site strengths? Are there any areas where we can improve? |
| This trial filled an identified gap within the team’s research portfolio and/or provided an unmet option for the population under study. | Why not?  Were there similar studies open at the same time? | What need was filled with this study?  How valuable was this study to the research team and/or patients? |
| The scientific question remained relevant for the patient population under study. | Why not?  Did new treatment options become available during the course of the study? | Describe the patient’s and research team’s interest at all stages of the research process. |
| There were one or more competing studies which opened during the course of this trial. | If no competing studies were identified, was recruitment as strong as possible? Why or why not? | If competing studies were identified, how did they impact the overall success of this study?  Was there a plan for how competing studies would be handled? If yes, what? If no, why not? |
| This trial generated new ideas for future research and/or lead to a change in standard practice. | If no, what was the value of the research?  If this was a negative study, how will this affect future studies of interest? Where do your interests now lie? | If yes, what ideas were generated?  Did the trial further a particular research interest and/or area of work already taking place within the team?  Compared to the start of study enrolment, has the research team’s interest in the scientific question increased or decreased?  How does the team plan to build on this research?  Are there future studies planned based off this study? If yes, are you interested to participate in these future studies? |

**Evaluation of recruitment**

| **LL Questionnaire Statements** | **Related Open Discussion Questions** | |
| --- | --- | --- |
| **Negative LL Questionnaire Response** | **Positive LL Questionnaire Response** |
| Recruitment to this trial went well at our site.  (Note: this ties in closely with the following question) | Why not? Is this a realistic expectation?  How can this be improved for future studies?  Was there insufficient population of potentially eligible patients to recruit from?  If study recruitment was problematic, where there any strategies employed to improve recruitment? If no, why not? | Why do you feel this study recruited successfully?  What recruitment strategies were used to maximize recruitment?  Did you pause to celebrate your success? Did you acknowledge you and your team’s achievements? If yes, how?  If study recruitment was problematic, what strategies were employed to improve recruitment? |
| We achieved our site target recruitment. | **If negative LL response AND the recruitment target WAS NOT met:**  What happened? How can we improve upon this for future studies?  How did you estimate your target? (for example, use of Decision Support, IT, or decision aids)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **If negative LL response AND the recruitment target WAS met:**  Why do you feel that recruitment was not as anticipated, even though you met your recruitment target? Was the target deflated? Why?  How did you estimate your target? (for example, use of Decision Support, IT, or decision aids) | **If positive LL response AND the recruitment target WAS NOT met:**  Were you kept aware of what the recruitment target was during the study? How did you try to reach this? Why do you feel there is a discrepancy? Was the target inflated? Why?  How did you estimate your target? (for example, use of Decision Support, IT, or decision aids)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **If positive LL response AND the recruitment target WAS met:**  How can we replicate this success?  How did you estimate your target? (for example, use of Decision Support, IT, or decision aids) |
| I frequently discussed this trial with my colleagues. | Why not?  What could have been done to encourage more open communications? | Describe the communication tools used to promote the study internally. How did this help? |
| I successfully championed this trial. | Why not?  What could you have done better?  Did the trial have another local champion who helped demonstrate the value of the trial to other clinicians and supported the study? | What did you do to successfully champion this study?  Did the trial have another local champion who helped demonstrate the value of the trial to other clinicians and supported the study?  How can we encourage champions for future studies? |
| I ran into obstacles regarding screening and/or recruitment. | How well did the research team do in identifying potential patients for the study?  Did you, your primary team, and the research team work well together to screen patients? | What obstacles were encountered? What can be done to improve this?  How well did the research team do in identifying potential patients for the study? Was this sufficient? If no, why not? |
| There were barriers and/or perceptions that negatively impacted recruitment. | Did the study have many components? (for example, optional studies, biopsies, PKs, etc)  What was the level of study burden to participants and their support systems, e.g., financial or time?  Were there patient perceptions that impacted recruitment, e.g., fear of placebos, suspicion about research, worries about costs, or practical matters like transportation distance? How were these overcome? | What were these barriers or perceptions? Were these overcome? If yes, how? If no, why not?  Did the study have many components? (for example, optional studies, biopsies, PKs, etc)  What was the level of study burden to participants and their support systems, e.g., financial or time?  Were there patient perceptions that impacted recruitment, e.g., fear of placebos, suspicion about research, worries about costs, or practical matters like transportation distance? Were any measures in place for addressing these concerns at the outset?  Was feedback regarding perceptions/barriers given to the sponsor? Was the sponsor receptive to your comments? |

**Evaluation of the institution’s infrastructure**

| **LL Questionnaire Statements** | **Related Open Discussion Questions** | |
| --- | --- | --- |
| **Negative LL Questionnaire Response** | **Positive LL Questionnaire Response** |
| The protocol required specialized training of staff or new equipment. | N/A | Did training occur in a timely manner?  Was training adequate? |
| Trial specific information was easy to find and readily available. | Are you aware of where information can be found? (for example, shared drives, emails, online, etc)  What can we do to make the information more readily available? | Where did you find this information? Was this an appropriate place? Will you continue to get information in this manner? |
| The institution was able to meet the protocol requirements. | What services/capacity issues arose? How did this affect recruitment?  What measures need to be put in place to enable the site to perform future related studies?  How well did you anticipate issues that were likely to come up and plan solutions early to minimize impact to study performance? | What needs/services were required for the study? How were these provided?  Did new needs arise during the course of the study? How was this addressed?  How well did you anticipate issues that were likely to come up and plan solutions early to minimize impact to study performance? |
| I had the necessary capacity and resources to recruit to this study. | How did this affect the study performance?  What can be done to increase capacity? | How did you manage this workload? |

**Evaluation of the study team**

| **LL Questionnaire Statements** | **Related Open Discussion Questions** | |
| --- | --- | --- |
| **Negative LL Questionnaire Response** | **Positive LL Questionnaire Response** |
| The research team worked well together. | Why not? | Why? |
| There was sufficient staff and investigator buy-in. | Why not?  Did you reach out to community partners? If no, why not? | How was buy-in encouraged?  Did you reach out to community partners? If so, what forum for communicating did you use? How effective do you feel it was? |
| Questions/concerns related to the trial were addressed as they came up. | Why not? | How was this handled? |
| I felt ownership for the success of this trial. | Why not? Was this communicated to the study team?  Was staff provided opportunity to provide input early in the trial and throughout? | How was this feeling encouraged?  Was staff provided opportunity to provide input early in the trial and throughout? |
| Promotional materials were used to help promote the trial internally. | Why not?  Would you be interested in using promotional tools for future studies? | Describe the materials used. How did this help to promote the study? Would you use tools such as these again? |
| I experienced conflicts regarding this trial (either personal or interpersonal). | If no, were conflicts avoided? How? Were conflicts handled directly and appropriately? How? | If yes, how was this handled? Was assistance required? |
| The experience of working with the research team was a positive one. | Why not?  Do you feel clinician and staff engagement has been hampered as a result of their experience participating in this study? How?  Would you work with this same team again? | Do you feel clinician and staff engagement has grown as a result of their experience participating in this study? How?  Would you work with this same team again? |

**Evaluation of the site/sponsor relationship**

| **LL Questionnaire Questions** | **Related Open Discussion Questions** | |
| --- | --- | --- |
| **Negative LL Questionnaire Response** | **Positive LL Questionnaire Response** |
| I felt well-supported by the sponsor. | Did you receive satisfactory answers to your question and were they timely? If no, why not?  Are there certain aspects of working with the sponsor that were better/worse than others? If so, what? | Did you receive satisfactory answers to your question and were they timely?  Are there certain aspects of working with the sponsor that were better/worse than others? If so, what? |
| The experience of working with the sponsor was a positive one. | How would you describe your relationship with the study sponsor?  Why not? Did the sponsor have unrealistic demands? What were they?  Was there a CRO involved? If so, what was your impression of the CRO? How does this affect the sponsor relationship? | How would you describe your relationship with the study sponsor?  Were the sponsor’s demands realistic or unrealistic? How so? If they were unrealistic, how was this overcome?  Was there a CRO involved? If so, what was your impression of the CRO? How does this affect the sponsor relationship? |
| I think the sponsor feels positively about our site, given our site's performance in this trial. | What do you think the sponsor would say about you, your study team, and our site now that the study is complete?  Would you work with this sponsor again? Why or why not?  If there was a CRO, would you work with the CRO again? Why or why not?  Do you think the sponsor/CRO would want to work with us again? Why or why not?  During the course of the study, how might have the site/sponsor relationship been strengthened? | What do you think the sponsor would say about you, your study team, and our site now that the study is complete?  Would you work with this sponsor again? Why or why not?  If there was a CRO, would you work with the CRO again? Why or why not?  Do you think the sponsor/CRO would want to work with us again? Why or why not?  How were you able to develop a positive relationship? What is most influential is developing a strong working relationship? |

# Part 3: Summary & Next Steps

**The following 3 questions should be asked for ALL trials, regardless of the answers given:**

1. What are the top 3 things you know now that you wish you had known at the start of this trial?
2. What went well during the trial? How would you re-create this for future trials?
3. What did not go well? How would you avoid this for future trials?