# phuse

# KPI

**KPIs & Metrics Project:** **Year 2 Report**

# Summary

This report presents the results of the Year 2 Key Performance Indicators (KPIs) & Metrics Project industry survey. Following the Year 1 survey feedback the KPI terminology and definitions were extended and strengthened, the PHUSE KPI schematic re-published, and the survey significantly redesigned. Responses to the survey were received from a similar number of respondents as in Year 1; these are reported here. The results are reflective of general experience and are considered good first candidates for industry benchmark measures. However, further work to confirm and consolidate these results is required before they could be claimed to reflect any overall industry practice.

# Introduction

The initial goal of the KPIs & Metrics Project (started 2018) was twofold: first, to develop, collect and publish a set of Key Performance Indicators (KPIs) to measure the quality and duration of the tasks that fall under the statistical programming umbrella, and second, to survey the industry and report benchmark values for these KPIs. Three principal deliverables were delivered during Year 1: a set of terminology and metrics definitions, an interactive web-based terminology map (schematic) to navigate and review the definitions, a Year 1 survey questionnaire, and an industry survey and report: "Key Performance Indicators (KPIs) & Metrics Project: Year 1 Report" (1).

The Year 2 part of the project continued this work, concentrating efforts in two major areas: revision and additions to the terminology and definitions, and revising, re-running, and reporting the industry survey (this report).

# KPIs & Metrics Project Team

The KPIs & Metrics Project team consisted of volunteers from across the pharmaceutical industry and contract research organisations, under the leadership of Yvonne Moores (PHUSE Project Lead) and Andy Richardson (Co-Lead).

The full list of contributing volunteers can be found at:
*www.phusewiki.org/wiki/index.php?title=Key_Performance_Indicators_%26_Metrics_(KPI)*

# Methods

**1. KPI Terminology and Definitions:**
Each terminology definition and KPI definition was revisited by the project team in light of experience with the Year 1 survey and specific feedback with regards to the value and each KPI. The team also incorporated industry feedback requesting additional metrics be considered that were not included in the original definition and terminology work (in particular, "Topline Results", the important interim deliverable requested for many clinical trials).

**2. KPI Schematic:**
The work in (1) above necessitated a revision of the KPI schematic (to add or remove items), which was also redesigned to aid clarity (Figure 1). The full interactive version is available at *www.phuse.eu/kpi-metrics-definitions-terminology-map*, where users will also find the final revised terminology and KPI definitions. Key additions included "Topline Results" (discussed earlier), study execution timepoints (FPFV, LPLV), and their related "time to" metrics (e.g. "Locked Database" to "Topline Results"). Better and clearer examples of how to determine many of the metrics were also added.

**3. Year 2 Survey:**
The KPI terminology and definition revisions were incorporated into the Year 2 survey.

**a. Survey Instrument:**
Feedback from the Year 1 survey was used to develop a revised Survey Instrument for the Year 2 survey. Each question was reviewed and (potentially) revised, questions removed where poor responses or lack of clarity was reported, and new metrics questions added. Overall, the number of questions was reduced and more helpful guidance to completion added (see Appendix).

**b. Conduct of the Survey:**
Harris Interactive (an independent survey company) was again commissioned to run the survey using their web-based survey tools. 61 companies were invited to participate in the survey and results returned to PHUSE as de-identified (no company details provided) responses. Survey participants were requested to complete the survey within a 3-month period (Oct 2019 to Jan 2020), which was extended to Mar 2020 following minimal take-up during the initial requested reporting period.

**4. Analysis & Reporting:**
Analysis and reporting of the results of the Year 2 survey adopted the same methodology as Year 1. The responses to all survey questions are presented; however, only questions with 5 or more responses are summarised. The number of respondents — minimum, median and maximum — are provided for each question summarised. No inferential statistics were calculated.

**Figure 1: Revised KPI Schematic following the Year 1 Survey and Report Feedback**
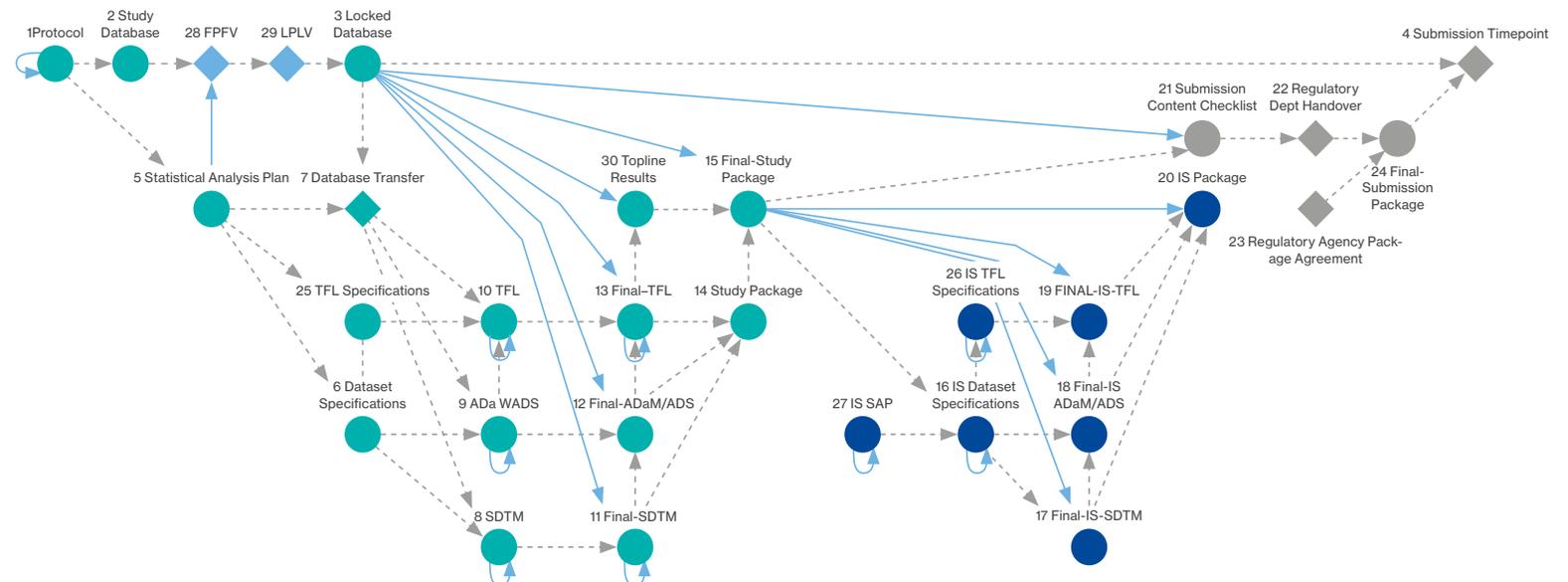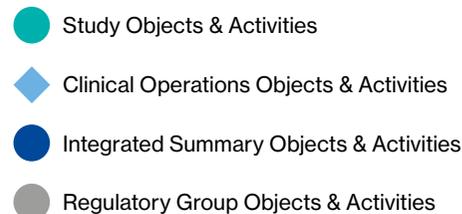
# Results

The survey was sent to 61 companies. Of these, 7 companies provided responses by the end of the 5-month survey period (11%). Of the 20 questions in the survey, 45% (9/20) had sufficient responses to be reported. Of the 7 companies who responded, 2 were CROs and 5 were pharmaceutical companies.

The tables and figures that follow show the results from the questions where 5 or more responses were received. Minimum, median and maximum values are shown. Table 1 presents the results where the KPI is a quality/efficiency metric (e.g. % TFLs revised). Table 2 presents the results where the KPI is measuring a performance/time metric

(e.g. average time taken). Table 3 shows those questions where fewer than 4 responses were received and therefore are not reported.

The figures present the same data graphically. Figure 2 shows the quality/efficiency results; Figure 3 the performance/time results.

**Table 2: Year 2 Survey Results: Performance KPI Responses (days)**

| ID | Question | Phase of Study | N | Minimum | Median | Maximum |
|---|---|---|---|---|---|---|
| MQ4 | What is the average time from Database Lock to Topline Report? | Early | 5 | 3 | 8 | 20 |
| | | Late | 6 | 3 | 9 | 30 |
| MQ5 | What is the average time from Database Lock to final SDTM datasets? | Early | 5 | 1 | 2 | 4 |
| | | Late | 6 | 1 | 2.5 | 45 |
| MQ8 | What is the average time from Database Lock to final ADaM datasets? | Early | 5 | 3 | 6 | 23 |
| | | Late | 7 | 3 | 7 | 45 |
| MQ11 | What is the average time from Database Lock to final TFLs? | Early | 5 | 9 | 21 | 23 |
| | | Late | 6 | 12 | 21 | 60 |

**Table 1: Year 2 Survey Results: Quantity KPI Responses (N)**

| ID | Question | Phase of Study | N | Minimum | Median | Maximum |
|---|---|---|---|---|---|---|
| MQ3 | What is the average number of Database Unlocks (re-locks) after the final lock of the study? | Early | 6 | 0 | 0.065 | 1 |
| | | Late | 6 | 0 | 0 | 1.5 |
| MQ6 | What is the average number of SDTM domains that are included in a final study package? | Early | 5 | 25 | 27 | 32 |
| | | Late | 6 | 25 | 32.5 | 40 |
| MQ9 | What is the average number of ADaM domains that are included in a final study package? | Early | 5 | 7 | 12 | 18 |
| | | Late | 6 | 13 | 19 | 30.46 |
| MQ12 | What is the average number of TFLs that are included in a final study package? | Early | 5 | 80 | 114 | 277 |
| | | Late | 5 | 150 | 269 | 400 |

**Table 3: Questions with Fewer than 4 Responses**

| ID | Question |
|---|---|
| MQ1 | What is the average number of versions of the Statistical Analysis Plan (SAP) after it was initially set as final? |
| MQ2 | What is the average time from approved SAP to study First Patient First Visit? |
| MQ7 | What is the target number of SDTM domains that your company aims to deliver in a final study package? |
| MQ10 | What is the target number of ADaM domains that your company aims to deliver in a final study package? |
| MQ13 | What is the target number of TFLs that your company aims to deliver in a final study package? |
| MQ14 | What is the average time from Study Database Lock to Final Study Package Complete? |
| MQ16 | What is the average time from Last Study Database Lock to Submission Content Checklist? |
| MQ17 | What is the average time from Final Study Package to Final IS SDTM available? |
| MQ18 | What is the average time from Final Study Package to Final IS ADaM available? |
| MQ19 | What is the average time from Final Study Package to Final IS TFLs available? |
| MQ20 | What is the average time from Final Study Package to Final IS Package available? |

# **Results** Continued
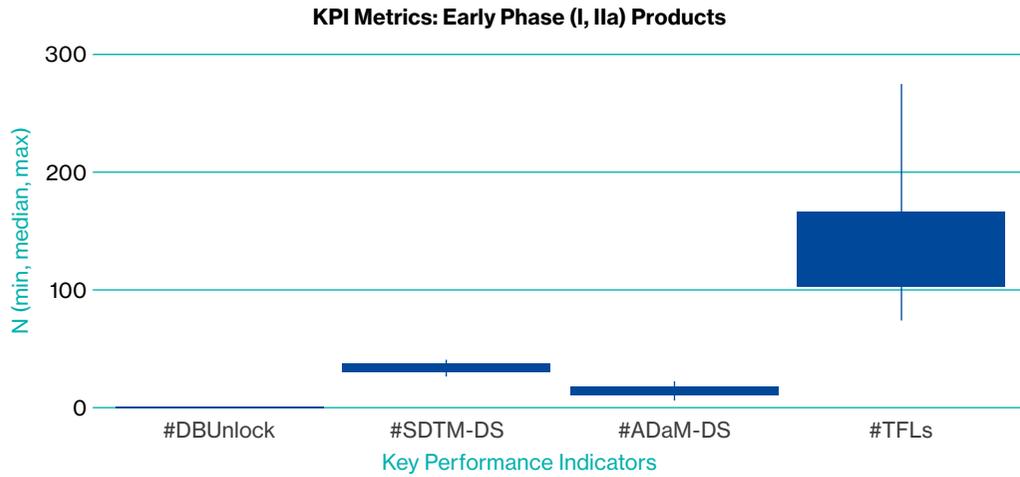
KPI Metrics: Early Phase (I, IIa) Products

KPI Metrics: Early Phase (I, IIa) Timelines

KPI Metrics: Late Phase (IIb, III) Products

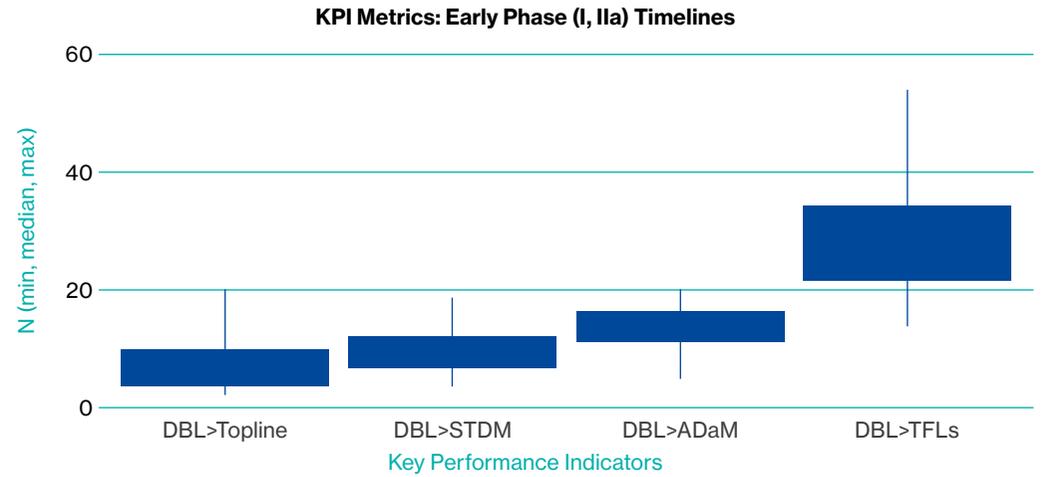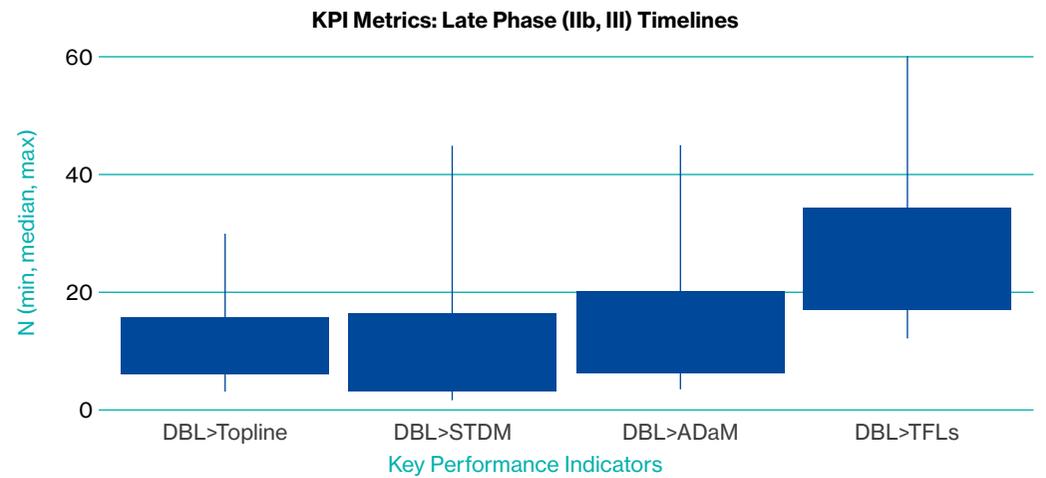KPI Metrics: Late Phase (IIb, III) Timelines

# Discussion

The aims and deliverables for the KPIs & Metrics Project, as it completes its second year, fall simply into highlights and lowlights. The highlights of the year have been the continued work on the KPI terminology and metrics definitions, which has been strengthened, added to, and re-published as an updated publicly available PHUSE resource. The lowlight has been the poor response to the industry survey, which has not permitted the project to establish clear benchmark metrics in support of programming operational efficiency.

The KPI terminology and metrics definitions received constructive and useful feedback following the Year 1 work. It was recognised that some of the metrics should not be promoted as core benchmark metrics (e.g. metrics directly concerning dataset specifications), whilst the addition of clinical operations timepoints (FPFV, LPLV) and "topline results" strengthens the overall measures. These and other changes were implemented in a redesign of the KPI schematic, now available via the PHUSE website.

The Year 1 survey feedback was also instrumental in revising and simplifying the survey questionnaire and making better "how to complete" examples available. As previously, these were used to implement an online survey using an independent survey company. 61 organisations were invited to contribute and respond to the survey, of which only 7 responses with sufficient data to report were completed. No clear reasons for this poor response can be determined. "Don't collect this", "doesn't apply to me", "data has to be collected and collated from multiple sources", "I don't have permission to provide it", and "don't understand the metric" may be in part amongst the reasons.

This has meant that the hoped-for outcome of the original project — to be able to establish an annual KPI survey and report KPI trends — is not practically possible with this level of interest. A cursory examination comparing the results for both years shows similar results where the results can be compared, but the low Ns do not permit much more to be concluded.

Although it is not possible to claim any broad industry consensus from the Year 2 results (due to the small number of responses received), the results do show expected trends. For example, the ratio of average number of ADaM datasets and TFL to SDTM datasets (Figure 2) is not unexpected. Similarly, the "time to" results reflect reported experience (Figure 3). Unfortunately, the small numbers and wide ranges to do permit more to be concluded; however, it is interesting to speculate, for example, what may operationally be contributing to the different "Early" and "Late" timeline trends in Figure 3. These results, if extended and confirmed, give some hope that these metrics are good candidates for industry benchmarks.

In its current form the KPIs & Metrics Project will not continue into a third year. The work to date will remain publicly available as a resource for both PHUSE and others. Future work in this area could consider projects designed to assist with establishing KPI metrics (perhaps a "KPI Metrics Implementation Guide") or serve as a reporting framework for organisations to use when presenting operational efficiencies at conferences or elsewhere.

We would like to take this opportunity to thank all the members of the KPIs & Metrics Project team for their contributions over the course of the project.

# References

1. Key Performance Indicators (KPIs) & Metrics Project: Year 1 Report. *www.phuse.eu/kpi-report-phase1-download*

# **Appendix** Year 2 Survey Questionnaire

| Question Number | Schematic ID/Question Number | Survey Question | Method of Calculation | Notes |
|---|---|---|---|---|
| MQ1 | 5T5 | "What is the average number of versions of the Statistical Analysis Plan (SAP) after it was initially set as final?" | N versions | "Metric is average N across studies, which is calculated as Number of Versions of Statistical Analaysis Plan issued after SAP is first set as Final/Number of studies with final SAP in the past 12 months.<br><br>Example: Out of 3 Phase III studies that had a final SAP in the past 12 months, one study required an SAP update twice (2 new versions of SAP) and the remainder of the studies did not require updates. The average is (3+1+1)/3 = 1.67." |
| MQ2 | 5T28 | What is the average time from approved SAP to study First Patient First Visit? | Date FPFV – date Statistical Analysis Plan approved (days) | Metric may be negative (if the SAP is approved/finalised after FPFV) |
| MQ3 | 3T3 | What is the average number of database unlocks (relocks) after the final lock of the study? | (N unlocks) | "Metric is average unlocks (relocks) across studies, which is calculated as Number of Unlocks/Number of Studies in the past 12 months.<br><br>Example: Out of 5 Phase III studies that had a final lock in the past 12 months, one study unlocked (relocked) twice and the remainder of the studies did not unlock (relock). The average is 2/5 = 0.40." |
| MQ4 | 3T30 | What is the average time from database lock to Topline Report? | Date Topline Report completed – date Study Database locked as final (days) | "Metric is average across studies of the number of working days from database lock until Topline Report has been completed.<br><br>Example: One study had database lock on Monday June 1. The QCed and validated Topline Report was released on Wednesday June 10. June 1 to June 10 is 8 working days.<br><br>For 3 other studies in that 12-month period, Topline Report occurred after 10 days, 15 days and 7 days. So, the average for the company is (8+10+15+7)/4 = 10." |
| MQ5 | 3T11 | What is the average time from database lock to final SDTM datasets? | Date final SDTM datasets completed – date database locked as final (in working days) | "Metric is average across studies of the number of working days from database lock until final SDTM datasets have been completed. Final means after all SDTM datasets have been revised and they require no further revision or modification.<br><br>Example: One study had database lock on June 1. The first draft of QCed and validated SDTM datasets were released on June 10. During the creation of the ADaM datasets an error was discovered in one of the SDTM datasets. That dataset was re-released on June 22. No more errors were found.<br><br>June 1 to June 22 is 3 working weeks and 1 working day. So, for this study, the number of working days from Database Lock to Final SDTM datasets is calculated as 16 days.<br><br>For 3 other studies in that 12-month period, final SDTM datasets occurred after 10 days, 32 days and 5 days. So, the average for the company is (16+10+32+5)/4 = 15.75." |

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|---|---|---|---|---|
| MQ6 | 11T11 | What is the average number of SDTM domains that is included in a Final Study Package? | Average number of SDTM domains that are included in a Final Study Package | "Main and Supplemental datasets are counted ONCE as ONE domain.<br><br>Metric is average count of number of SDTM domains across studies.<br><br>Example: 1: 21 SDTM domains, 2: 24 SDTM domains, 3: 32 SDTM domains.  Percentage = (21+24+32)/3 =25.7 domains across studies.  " |
| MQ7 | 11aT11a | What is the target number of SDTM domains that your company aims to deliver in a Final Study Package? | Target number of SDTM domains that your company aims to deliver in a Final Study Package | Company target on expected number of SDTMs needed for a study. |
| MQ8 | 3T12 | What is the average time from database lock to final ADaM datasets? | Date final ADaM datasets completed – date database locked as final (in working days) | "Metric is average across studies of the number of working days from database lock until final ADaM datasets have been completed. Final means after all ADaM datasets have been revised and they require no further revision or modification.<br><br>Example: One study had database lock on June 1. The first draft of QCed and validated ADaM datasets were released on June 10. During the creation of the TFLs an error was discovered in one of the ADaM datasets. That dataset was re-released on June 22. No more errors were found.<br><br>June 1 to June 22 is 3 working weeks and 1 working day. So, for this study, the number of working days from Database Lock to Final ADaM datasets is calculated as 16 days.<br><br>For 3 other studies in that 12-month period, final ADaM datasets occurred after 10 days, 32 days and 5 days. So, the average for the company is (16+10+32+5)/4=15.75." |
| MQ9 | 12T12 | What is the average number of ADaM domains that is included in a Final Study Package? | Average number of ADaM domains that is included in a Final Study Package | "Metric is average count of number of ADaM domains across studies.<br><br>Example: 1: 12 ADaM domains, 2: 15 ADaM domains, 3: 10 ADaM domains.  Average = (12+15+10)/3 = 12.3 ADaM domains across studies." |
| MQ10 | 12aT12a | What is the target number of ADaM domains that your company aims to deliver in a Final Study Package? | Target number of ADaM domains that your company aims to deliver in a Final Study Package | Company target on expected number of ADaMs needed for a study. |

# **Appendix** Year 2 Survey Questionnaire

| Question Number | Schematic ID/Question Number | Survey Question | Method of Calculation | Notes |
|---|---|---|---|---|
| MQ11 | 3T13 | What is the average time from database lock to final TFLs? | Date final TFLs completed – date database locked (in working days) | "Metric is average across studies of the number of working days from database lock until final TFLs have been completed. Final means after all TFLs have been revised and they require no further revision or modification. Example: One study had database lock on June 1. The first draft of QCed and validated TFLs were released on June 10. During the statistical review an error was discovered in one of the TFLs. That TFL was re-released on June 21. It turned out that a footnote still required adaption. Therefore, that TFL was re-released again on June 22. No more errors were found. June 1 to June 22 is 3 working weeks and 1 working day. So, for this study, the number of working days from Database Lock to Final TFLs datasets is calculated as 16 days. For 3 other studies in that 12-month period, final TFLs occurred after 10 days, 32 days and 5 days. So, the average is for the company is (16+10+32+5)/4=15.75." |
| MQ12 | 13T13 | What is the average number of TFLs that is included in a Final Study Package? | Average number of TFLs that is included in a Final Study Package | "Metric is average count of number of TFLs across studies. Example: 1: 210 TFLs, 2: 240 TFLs, 3: 320 TFLs. Percentage = 210+240+320/3 = 257 TFLs across studies. " |
| MQ13 | 13aT13a | What is the target number of TFLs that your company aims to deliver in a Final Study Package? | Target number of TFLs that your company aims to deliver in a Final Study Package | Company target on expected number of TFL outputs needed for a study. |
| MQ14 | 3T15 | "What is the average time from study database lock to Final Study Package Complete? " | Date Final Study Package completed – date study database locked (days) | "Metric is average across studies of the number of working days from database lock until Final Study Package has been completed. Final Study Package Complete is defined as but not limited to the collection of study SDTM datasets, ADaM or analysis datasets, TFLs, Reviewer's Guides, Define files and aCRF that are required to be included in the Clinical Study Report and Clinical Study Package where a determination has been made that they require no further revision or modification. " |
| MQ15 | | Did you complete any submissions in the 12-month KPI reporting period? | | |
| MQ16 | 3T21 | What is the average time from Last Study Database Lock to Submission Content Checklist? | Date Submission Content Checklist completed – date final database locked (days) | "Metric is the time from the last final study, if many studies are to be submitted together. " |

# **Appendix** Year 2 Survey Questionnaire

| Question Number | Schematic ID/Question Number | Survey Question | Method of Calculation | Notes |
|---|---|---|---|---|
| MQ17 | 15T17 | What is the average time from Final Study Package to Final IS SDTM available? | Date of Final IS SDTM – date of Final Study Package available (days) | "The metric refers to the Final Study Package for the LAST study that will be included in the IS SDTM, e.g. 4 studies are included in the Final IS SDTM (IS SDTM 1). Study 1–3 are available Aug–Oct (before Study 4). Study 4 is completed on Nov-10 (i.e. the Study 4 Final Study Package is now available). The calculation of the metric is from the date the Study 4 package is available to the date the IS SDTM are final (Nov-12). Final IS SDTM from Final Study Package for LAST Study: Nov-12 – Nov-10 = 2 days.<br><br>Metric is the average N days for all Final IS SDTM completed in the last 12 months, i.e:<br><br>Final IS SDTM 1: Nov-12 – Nov-10 = 2 days<br>Final IS SDTM 2: 6 days<br>Final IS SDTM 3: 1 day<br><br>Average Time from Last Final Study Package to Final IS SDTM = (2+6+1)/3 = 3 days." |
| MQ18 | 15T18 | What is the average time from Final Study Package to Final IS ADaM available? | Date of Final IS ADaM – date of Final Study Package available (days) | "The metric refers to the Final Study Package from the LAST study that will be included in the IS ADaM/ADS, e.g. 4 studies are included in the Final IS ADaM/ADS (IS ADaM/ADS 1). Study 1–3 are available Aug–Oct (before Study 4). Study 4 is completed on Nov-10 (i.e. the Study 4 Final Study Package is now available). The calculation of the metric is from the date the Study 4 package is available to the date the ADaM/ADS are final (Nov-17). Final IS ADaM from Final Study Package for LAST Study: Nov-17 – Nov-10 = 7 days.<br><br>Metric is the average N days for all Final IS ADaM/ADS completed in the last 12 months, i.e:<br><br>Final IS ADaM/ADS 1: Nov-17 – Nov-10 = 7 days<br>Final IS ADaM/ADS 2: 2 days<br>Final IS ADaM/ADS 3: 6 days<br><br>Average Time from Last Final Study Package to Final IS ADaM/ADS = (7+2+6)/3 = 5 days." |

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| Question Number | Schematic ID/Question Number | Survey Question | Method of Calculation | Notes |
|---|---|---|---|---|
| MQ19 | 15T19 | What is the average time from Final Study Package to Final IS TFLs available? | Date of Final IS TFLs – Date of Final Study Package Available (days) | "The metric refers to the Final Study Package from the LAST study that will be included in the IS TFLs, e.g. 4 studies are included in the Final IS TFLs (IS TFLs 1). Study 1–3 are available in Aug-Oct (before Study 4). Study 4 is completed on Nov-10 (i.e. the Study 4 Final Study Package is now available). The calculation of the metric is from the date the Study 4 package is available to the date the IS TFLs are final (Nov-25). Final IS TFLs from Final Study Package for LAST Study: Nov-25 – Nov-10 = 15 days.<br><br>Metric is the average N days for all Final IS TFLs completed in the last 12 months, i.e.:<br><br>Final IS TFLs 1: Nov-25 – Nov-10 = 15 days<br>Final IS TFLs 2: 12 days<br>Final IS TFLs 3: 18 days<br><br>Average Time from Last Final Study Package to Final IS ADaM/ADS = (15+12+18)/3 = 15 days." |
| MQ20 | 15T20 | What is the average time from Final Study Package to Final IS Package available? | Date of Final IS Package – date of Final Study Package available (days) | "The metric refers to the Final Study Package from the LAST study that will be included in the IS Package, e.g. 4 studies are included in an Final IS Package (IS Package 1). Study 1–3 are available Aug–Oct (before Study 4). Study 4 is completed on Nov-10 (i.e. the Study 4 Final Study Package is now available). The calculation of the metric is from the date the Study 4 package is available to the date the IS Package is final (Nov-20). Final IS Package from Final Study Package for LAST Study: Nov-20 – Nov-10 = 10 days.<br><br>Metric is the average N days for all Final IS packages completed in the last 12 months, i.e.:<br><br>Final IS Package 1: Nov-20 – Nov-10 = 10 days<br>Final IS Package 2: 15 days<br>Final IS Package 3: 20 days<br><br>Time from Last Final Study Package to Final IS Package = (10+15+20)/3 = 15 days. " |