

Leadership Report: User Guide

Description of Report

These reports display business process metrics for protocols for multiple Clinical Research Units (CRUs). The reports present timelines (average and medians) of business processes across Fiscal Years, Fiscal Quarters, and Fiscal Periods. Each metric has a start date and an end date and is measured in business days (i.e., not a Duke holiday and not a weekend).

The following metrics are included in the reports, with the start point given first, followed by the end point (after **to**).

1. Principal Investigator Signature to Institutional Approval
2. Principal Investigator Signature to Clinical Research Unit (CRU) Review
3. CRU Review to CRU Approval
4. CRU Approval to IRB Review
5. Legal Contract Negotiation
6. OCRC Received to Contract Execution
7. Contract Execution to Institutional Approval
8. IRB Review to IRB Approval
9. IRB Approval to Institutional Approval
10. For studies that are labeled “billing risk”, Institutional approval to first enrollment.

These metrics are calculated for all protocols that fall under the following eight funding sources:

- NIH Billing Risk
- NIH Non-Billing Risk
- Federal Other Billing Risk
- Federal Other Non-Billing Risk
- Industry Billing Risk
- Industry Non-Billing Risk
- Internal Billing Risk
- Internal Non-Billing Risk

For all of the metrics displayed above, the start point and end point must have a date to be included in the calculations. For example, if a protocol has a date for Principal Investigator Signature, but none for Institutional Approval (it may be awaiting Institutional Approval), it is not included in any calculation (i.e., nulls are excluded).

Report Use (Main Report)

Upon accessing the report, first click on **Refresh Values** to bring up the list of Fiscal Years.

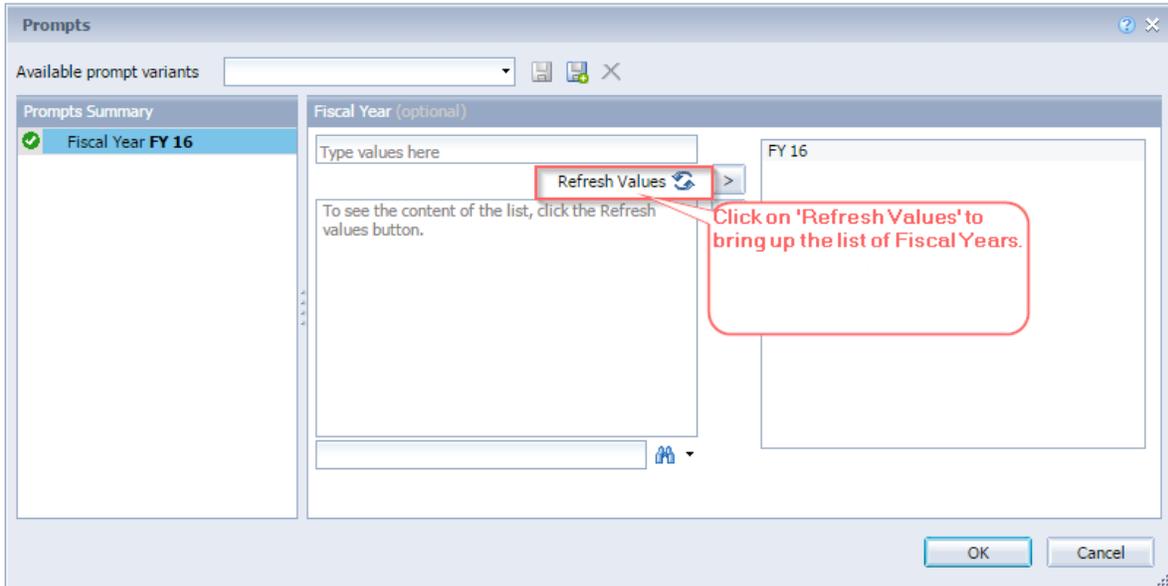


Figure 1. Fiscal Year Prompt

Click on the Fiscal Year you are interested in, and then click on the arrow to move it over into the selected value column. You may select multiple fiscal years.

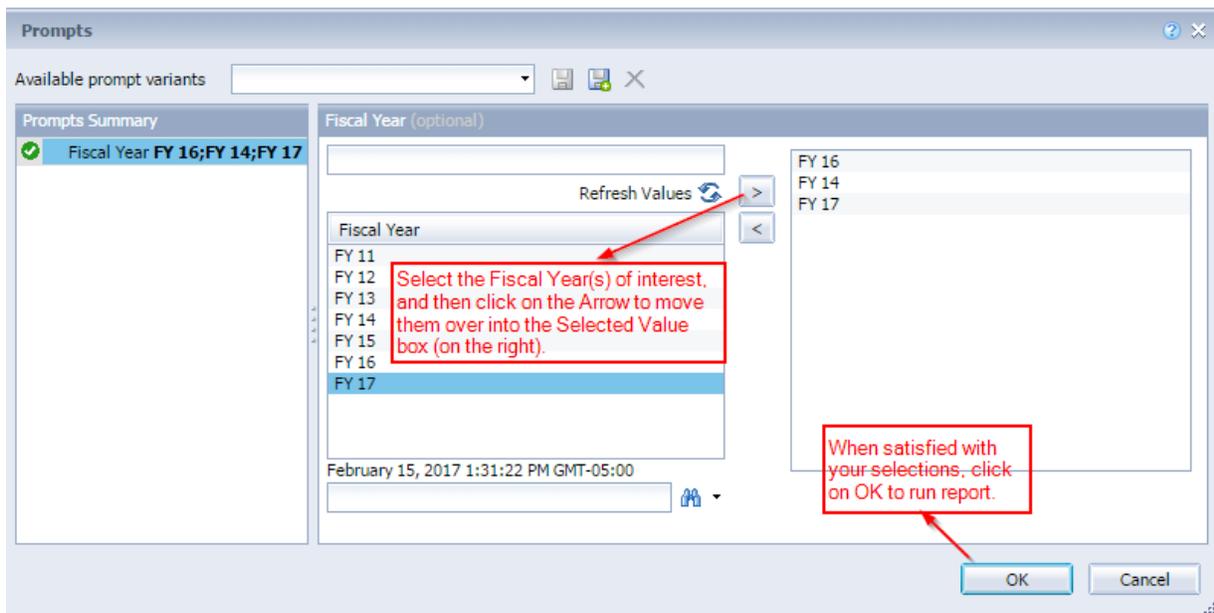


Figure 2. Fiscal Year Selection

Running the report will result in the **Main Report** display, with two tabs. The first tab, **Time period under review**, breaks out studies by **Funding Source**.



Leadership Report

The time period under review for MWS40

CRU: ALL

Your user name and the CRU(s) available to you will display at the top of the report

PI Signature to Institutional Approval (Average)

Funding	FY 14	FY 16	FY 17
NIH BR			
NIH NBR			
Federal Other BR			
Federal Other NBR			
Industry BR			
Industry NBR			
Internal BR			
Internal NBR			
Avg(Avg)			

Value shown is an average of averages.

PI Signature to Institutional Approval (Median)

Funding	FY 14	FY 16	FY 17
NIH BR			
NIH NBR			
Federal Other BR			
Federal Other NBR			
Industry BR			
Industry NBR			
Internal BR			
Internal NBR			
Avg(Med)			

Value shown is an average of medians.

The first tab 'Time period under review', breaks studies out by Funding Source

Clicking on the second tab, 'Total time period under review' will not break out studies by funding source.

Time period under review

Total time period under review

Figure 3. Main Report Display (Funding Source)

Clicking on the second tab, **Total time period under review**, will display the studies in a cumulative manner (i.e., not broken out by funding source).

Note that the **Main Report** only displays one metric, Principal Investigator Signature to Institutional Approval. To see the other nine metrics, you must drill down into the **Detail Report**.



Figure 4. Main Report Display (Cumulative)

Drilling Down to the Detail Report

From the **Main Report**, you can drill down to the **Detail Report**, which includes all ten of the metrics given above. The **Detail Report** will display ONE fiscal year at a time. In the first tab, **Time period under review**, click on any of the values displayed in the Funding cells, for the Fiscal Year of interest.

PI Signature to Institutional Approval (Average)

Funding	FY 14	FY 16	FY 17
NIH BR			
NIH NBR			
Federal Other BR			
Federal Other NBR			
Industry BR			
Industry NBR			
Internal BR			
Internal NBR			
	FY 14	FY 16	FY 17
Avg(Avg)			

Click on the value displayed in one of the cells to drill down to the detail report.

Figure 5. Detail Report Drilldown

This leads to the following view, in a new tab within Business Objects. This view is the **Detail Report**. The Fiscal Year displayed will depend on which Fiscal Year column you clicked in.

FY 14

In this Detail View, we are just looking at Fiscal Year 2014.

FY 14 Average Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional Approval (Avg)		PI Signature to CRU Review (Avg)	CRU Review to CRU Approval (Avg)
NIH BR	1	1		1	1
NIH NBR	1	1		1	1
Federal Other BR	1	1		1	1
Federal Other NBR	1	1		1	1
Industry BR	1	1		1	1
Industry NBR	1	1		1	1
Internal BR	1	1		1	1
Internal NBR	1	1		1	1
TOTAL	10	10		10	10

FY 14 Median Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional Approval (Med)		PI Signature to CRU Review (Med)	CRU Review to CRU Approval (Med)
NIH BR	1	1		1	1
NIH NBR	1	1		1	1
Federal Other BR	1	1		1	1
Federal Other NBR	1	1		1	1
Industry BR	1	1		1	1
Industry NBR	1	1		1	1

Figure 6. Detail Report Display (FY 2014)

Here, all ten of the metrics are displayed for the selected Fiscal Year.

From this view, you can further drill down to a specific Fiscal Quarter.



Leadership Report
The time period under review

FY 14 Drill Down to Fiscal Quarter

Mousing over and clicking on the FY link at the top of the report will allow you to drill down to Fiscal Quarters within that Fiscal Year.

FY 14 Average Business Days

Figure 7. Detail Report Drilldown to Fiscal Quarter

This will change the display to Quarters within the Fiscal Year, starting with the First Quarter at the top. Scroll down through the report to see all four Quarters (if available).



Leadership Report The time period under review

Q1-14



FY 14 Average Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional Approval (Avg)		PI Signa
NIH BR				
NIH NBR				
Federal Other BR				
Federal Other NBR				
Industry BR				
Industry NBR				
Internal BR				
Internal NBR				
TOTAL				

FY 14 Median Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional Approval (Med)		PI Sign
NIH BR				
NIH NBR				
Federal Other BR				
Federal Other NBR				
Industry BR				
Industry NBR				
Internal BR				
Internal NBR				
TOTAL				

Q2-14



FY 14 Average Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional Approval (Avg)		PI Signa
NIH BR				
NIH NBR				
Federal Other BR				

Figure 8. Detail Report Fiscal Quarter Display

From the Fiscal Quarter view, you can further drill down to a specific Fiscal Period (month). Mouse-over the Fiscal Quarter of interest, and click to drill down to the Fiscal Periods within that quarter.



Leadership Report

The time period under review

Q1-14

Drill Down to Fiscal Period

Mouse over the Fiscal Quarter of interest and click to drill down to the Fiscal Periods within that quarter

FY 14 Average Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional A
NIH BR		
NIH NBR		
Federal Other BR		
Federal Other NBR		
Industry BR		
Industry NBR		

Figure 9. Detail Report Drilldown to Fiscal Period

Clicking on this will change the report to the following view:



Leadership Report

The time period under review

In this view, periods within the Fiscal Quarter are displayed.

01- FY 14



FY 14 Average Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional Approval (Avg)
NIH BR		
NIH NBR		
Federal Other BR		
Federal Other NBR		
Industry BR		

Figure 10. Detail Report Fiscal Period Display

In this view, the periods within the Fiscal Quarter are displayed, starting with the earliest period within the given quarter at the top.

Drilling 'Back Up'

Once you have drilled down to the lowest level of detail (Fiscal Period), it is possible to drill back up, to a Fiscal Quarter, and from the Fiscal Quarter, to a Fiscal Year.



Leadership Report

The time period under review

01- FY 14



Drill Up to Fiscal Quarter

Mouse over and click on the 'Drill Up' button to the right of Fiscal Period to drill back up to the parent Fiscal Quarter.

FY 14 Average Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional Approval (Avg)
NIH BR		
NIH NBR		
Federal Other BR		
Federal Other NBR		
Industry BR		
Industry NBR		

Figure 11. Detail Report Drillup to Fiscal Quarter

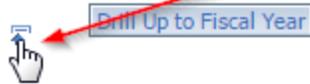
Once you are back in the Fiscal Quarter view, you can drill up again to the Fiscal Year.



Leadership Report

The time period under review

Q1-14



Mouse over and click on the 'Drill Up' button to the right of the Fiscal Period to drill back up to the parent Fiscal Year.

FY 14 Average Business Days

Funding	Number of eIRB Protocols	PI Signature to Institutional Approval
NIH BR		
NIH NBR		
Federal Other BR		

Figure 12. Detail Report Drillup to Fiscal Year

Drilling Down To Quarters/Periods in Main Report

It is also possible to drill down to quarters/periods within the **Main Report** itself. In doing this, the report will only display the one metric available in the **Main Report**, *PI Signature to Institutional Approval*. To drill down to a specific Fiscal Year in the main report, mouse over and select one of the Fiscal Years displayed in the top row.

PI Signature to Institutional Approval (Average)

Funding	FY 14	FY 16	FY 17
NIH BR			
NIH NBR			
Federal Other BR			
Federal Other NBR			
Industry BR			
Industry NBR			
Internal BR			
Internal NBR			

Mousing over and clicking on one of the Fiscal Years (top row) will drill down to that Fiscal Year

Figure 13. Main Report Drilldown

This will result in the following view. Note that when you drill down to a specific Fiscal Year (or Fiscal Quarter or Fiscal Period) on the Average or the Median table in the Main Report, the other table will not drill down to that level of specificity. It will only display the same Fiscal Year.

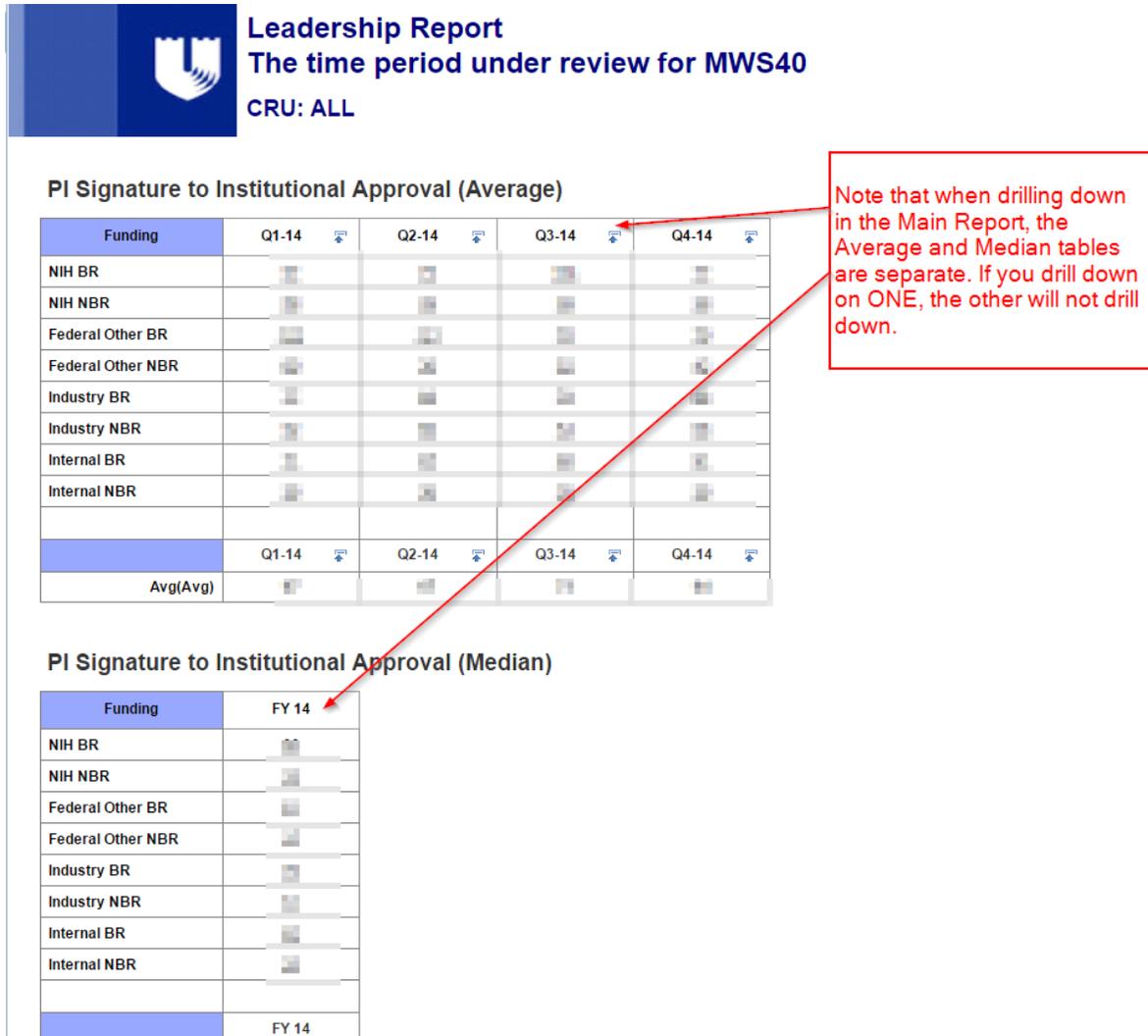


Figure 14. Main Report Drilldown

From this view, you can drill down to a specific Fiscal Quarter, and from there, to a specific Fiscal Period. You can also drill back up.