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1 Introduction

This document briefly describes the functionality available in the Duke Enrollment Dashboard. Note that dashboard enrollment numbers, as well as demographic information, are only available for protocols opened for enrollment after July 1, 2013 (MaestroCare Go-Live), as this data is pulled from MaestroCare. For protocols which opened to enrollment prior to July 1, 2013, data on enrollment numbers are not available.

1.1 Security

Please note: the information you see will be based on your role. If you are identified as a member of the School of Medicine Leadership group (or ‘Super-user’), you will be able to see across all Clinical Research Units (CRUs) available in the dashboard. Generally, if you are a Research Practice Manager (RPM), Financial Practice Manager (FPM), or CRU Medical Director, you will be restricted to viewing studies (protocols) within your own CRU. If you belong to neither of these groups, you will be restricted to viewing studies (protocols) for which you are a Principal Investigator (PI). A break-down of the security settings for the dashboard is shown below:

1. Leadership (Tier I or ‘Top Tier’ or ‘Super-user’)
   - Access to information on all protocols, across all CRUs
   - Examples: School of Medicine, Office of Research Informatics, and Duke Office of Clinical Research leadership or their designees

2. CRU Oversight (Tier II or ‘Middle Tier’)
   - Access to information on all protocols within their CRU
   - Examples: Research Practice Managers/Financial Practice Managers/Clinical Research Unit Directors or their designees

3. Principal Investigators (Tier III or ‘Bottom Tier’)
   - Access to information on a study (protocol) only if they are listed as that study’s Principal Investigator in eIRB

Finally, please note that access to the dashboard, contained in Business Objects, is only available when you are connected through the Duke network.

2 Dashboard Functionality

The following section describes the functionalities available in the dashboard and its behavior.

2.1 Filters

For any of the dashboard sections below, a filter may be applied to the Year (1). Additional filtering options include:

A filter for CRU (2), provided you have access to more than one CRU (e.g., you are a member of the Leadership group, or Tier I). The filter may be set to display All CRUs or a specific CRU. Only
CRUs that have enrollment will be available from this drop-down. Additionally, a filter may be applied to return Principal Investigators (PIs) (3) (available to those in Tier I and Tier II) or Studies (Protocols) (4) (available to those in Tier I, Tier II, and Tier III).

If you are not a member of the Tier I group, you will not be able to select different CRUs. If you are not a member of the Tier II group, you will not be able to select different PIs. You will still be able to see these filters; however, your selections will be restricted.

After a selection has been made in any of these filters, you must click Run (5) to update the dashboard display.

**Figure 1. Duke Enrollment Dashboard – Dashboard Filters**

When drilling down to a lower level of detail, the user must select the higher level of detail first (first select CRU, then PI, and, then, finally, study, or protocol). This is explained in greater detail in the section below.

### 2.1.1 CRU, PI, and Protocol Filters

Each of the filters described is single-select only.

At each drill-down level, you must first select the higher level detail, and then the lower level detail. Even with the proper security settings, you cannot immediately go from viewing enrollment across all CRUs to enrollment for a specific PI or enrollment in a specific study (protocol).

1. If a Tier I user wishes to see enrollment for a given PI (the next level of detail, after CRU), they must first select the CRU they wish to view.
2. To continue the next level of drill-down, you must then select a PI.
3. Finally, once the PI has been selected, then the individual study (protocol) may be selected.

The drill-down pathway is illustrated below:
Figure 2. Duke Enrollment Dashboard -- Drill-Down Pathway
When a Tier I user logs in, they will see the screen below:

![Duke Enrollment Dashboard](image)

**Figure 3. Duke Enrollment Dashboard – Tier I Log-In**

Note that enrollment counts for a CRU are displayed as orange bars.

2.1.1.1 **CRU Filter**

The CRU filter should be the starting point for those in Tier I (Super users/Leadership). The CRU filter drop-down will only display CRUs which have enrollment in their protocols. CRUs will be listed alphabetically. When a Tier I user selects a different CRU, the list of PIs available to select will change as well.
Again, for drilling down, this should be the first option selected.

Figure 4. Duke Enrollment Dashboard – CRU Filter

2.1.1.2 PI Filter

The PI filter should be the starting point for those in Tier II (CRU Oversight). When a Tier II user logs in, they will see the screen below:
Figure 5. Duke Enrollment Dashboard – Tier II Log-In

Note that enrollment counts for a PI are displayed as purple bars.

In the PI filter drop-down, PIs are listed in alphabetical order, by first name, as shown below.
When a Tier I or Tier II user selects a different PI, the list of studies (protocols) available to select will change as well.

2.1.1.3 Study (Protocol) Filter

The Study (Protocol) filter should be the starting point for those in Tier III (Principal Investigators). When a Tier III user logs in, they will see the screen below:
Figure 7. Duke Enrollment Dashboard – Tier III Log-In

Note that enrollment counts for a PI are displayed as cyan bars.

For Tier I and Tier II users, once both a CRU and PI have been selected, individual protocols may be selected. Protocols are listed numerically, in ascending order.
2.2 Mouse-Over Behavior

Note that for all of these charts, a mouse-over of the area of interest will return values from the chart. For example, if you are viewing the demographic data and would like to see more about the values shown, simply hover your mouse over the chart to learn more.
2.3 Printing

If you would like to print charts, you may do so using the Print option. You cannot print an individual chart; you can only print by section (e.g., Enrollment Trend, Demographics, Funding Source). See below for the print button:

![Duke Enrollment Dashboard – Printing](image)

Figure 10. Duke Enrollment Dashboard – Printing

2.4 Information Icon

Clicking the ‘Info’ icon will bring up this document.

![Duke Enrollment Dashboard - Information](image)

Figure 11. Duke Enrollment Dashboard - Information

3 Dashboards

The following section describes the charts contained within the dashboard. All dashboard tiers will have the same four sections, divided into three chart sections (Enrollment Trend, Demographics, and Funding Source), and one definitions section (Data Definitions).

3.1 Enrollment Trend

The three detail charts found in the Enrollment Trend section concern enrollment numbers, in total (both over time and as a snapshot). Note that, for all these charts, if you a member of the Leadership group (Tier I), you may search across CRUs, and if you are a RPM, FPM, or CRU Medical Director (Tier II), you may search across PIs within your CRU. Tier III users (Principal Investigators) will be restricted to viewing their own studies.

The charts found in this section are shown in Figure 12, below.
3.1.1 Quarterly Enrollment
This chart detail (1) displays total enrollment, by quarter. As this display shows, counts only begin in the third (calendar) quarter of 2013.

3.1.2 Quarterly Enrollment Over Time
This chart detail (2) displays total cumulative enrollment, by quarter.

3.1.3 Enrollment by CRU / Enrollment by PI / Enrollment by Study (Protocol)
For Chart 3, as shown below in Figure 13, you may choose to show total enrollment by CRU (only available to Tier I users), by PI (available to Tier I and Tier II users), or by Study (Protocol) (available to Tier I, Tier II, and Tier III users).
Figure 13. Duke Enrollment Dashboard – Enrollment by CRU/Enrollment by PI/Enrollment by Study (Protocol)

Note that when you cycle through CRU, PI, or Study (Protocol) options on this chart, you **do not** need to hit **Run** to update this chart.

### 3.2 Dashboard Sliders

For three charts in the **Enrollment Trend** section, discussed above, a slider will be made available under the chart, as shown in Figure 14.

#### 3.2.1 Enrollment Slider

For Charts 1 (Quarterly Enrollment) and 2 (Quarterly Enrollment Over Time), this slider allows you to zoom in on a particular time period of interest, viewing it in greater detail.

Figure 14. Duke Enrollment Dashboard – Dashboard Slider

To use the slider, hover your mouse over the slider (you may use both the beginning and ending slide tags), and move it to restrict the display to quarters of interest.

#### 3.2.2 Enrollment Group Slider

For Chart 3, Enrollment by CRU / Enrollment by PI / Enrollment by Study (Protocol), if Enrollment by CRU is selected, the slider will not appear, as the limited number of CRUs makes this unnecessary.
However, if you select enrollment by PI or by Study (Protocol), the slider may be used to restrict the display to PIs or Protocols of interest.

In the chart, PIs are shown in alphabetical order, arranged by first name, while studies (protocols) are shown in ascending numeric order.

Enrollment by PI is shown in Figure 15, while Enrollment by Study (Protocol) is shown in Figure 16.

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**Figure 15. Duke Enrollment Dashboard – Dashboard Slider for PI**
Figure 16. Duke Enrollment Dashboard – Dashboard Slider for Study (Protocol)

4 Demographics

The following four detail charts below concern demographic data. The demographic data is displayed as found in MaestroCare. There is no data cleansing – for example, there are enrolled patients whose race is shown as Hispanic. Per Office of Management and Budget (OMB) standards, Hispanic is not considered to be a racial category and was removed as an option for Race in MaestroCare Hyperspace.

Again, for these dashboards, note that if you have the requisite security settings, you may filter by CRU and by PI; all users may filter by study (protocol). The drill-down direction must proceed in the following manner: CRU to PI to Study (Protocol), and, after making your selection, you must select Run to update the dashboard display.
4.1 Enrollment by Gender
This chart detail (1) displays total enrollment, across all protocols, by gender.

4.2 Enrollment by Race
This chart detail (2) displays total enrollment, across all protocols, by race.

4.3 Enrollment by Age
This chart detail (3) displays total enrollment, across all protocols, by age.

Currently, there are three groupings:

- 0-18 Years
- 18 – 65 Years
• 65 + Years

Note that this age is based on the *age of the patient at the time of enrollment in the protocol.* Ages are rounded to the nearest whole number.

### 4.4 Enrollment by Ethnicity

This chart detail (4) displays total enrollment, across all protocols, by ethnicity.

### 5 Enrollment by Funding Source

This view shows the total enrollment, by funding source.

The funding sources are as follows:

- Industry
- Internal
- National Institute of Health (NIH)
- Federal – Other

This is based on information taken from Click’s electronic Institutional Review Board (eIRB), the IRB database for Duke. For more information, see Section 6.3.

Again, for these dashboards, note that if you have the requisite security settings, you may filter by CRU and by PI; all users may filter by study (protocol). The drill-down direction **must** proceed in the following manner: CRU to PI to Study (Protocol), and, after making your selection, you must select Run to update the dashboard display.
6 References

This section includes additional detail on the data sources used to create this dashboard.

6.1 Enrollment Trend Data Sources

Information on the source data for these enrollment numbers is found below:

Data Source: MaestroCare

Total enrollment is defined as the sum of distinct patient enrollment records in MaestroCare. The following MaestroCare statuses constitute enrollment:

- Completed Study
- Enrolled (IC obtained-under waiver or signed form)
- Enrolled Healthy Control Group Volunteer (IC obtained-under waiver or signed form)
- Enrolled No Bill Risk Protocol (IC obtained under waiver or signed form)
- Screen Failure
- Withdrawn by Patient
- Withdrawn by PI/study team
- Lost to contact

Figure 18. Duke Enrollment Dashboard – Funding Source
6.2 Demographics Data Sources

Demographic data is taken from *MaestroCare* (specifically, the *MC_PATIENT* table).

6.3 Funding Source Data Sources

Information on funding source is taken from the Click Institutional Review Board (eIRB). The following algorithm shown below in Table 1 was used to derive the funding source. This algorithm was developed in concert with the Duke Office of Clinical Research.

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<th>Rule</th>
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<td>NIH:</td>
<td>Protocols with at least one sponsor with SPONSOR_ALIAS in ('NIH','NCI','NEI','NHLBI','NHGRI','NIA','NIAAA','NIAID','NIAMS','NIBIB','NICHD','NIDCD','NIDCR','NIDDK','NIDA','NIEHS','NIGMS','NIMH','NIMHD','NINDS','NINR','NLM','NCCAM','NCATS','DIADS')</td>
</tr>
<tr>
<td>Federal - Other:</td>
<td>Protocols NOT NIH sponsored and at least one sponsor found where sponsor_type like '%Federal%' or sponsor_type like '%Non-profit%' or sponsor_type like '%Government%'</td>
</tr>
<tr>
<td>Industry:</td>
<td>Protocols NOT NIH sponsored or Federal-Other sponsored and at least one sponsor found where sponsor_type like '%Industry%'</td>
</tr>
<tr>
<td>Internal:</td>
<td>Protocols NOT in above categories AND (s.sponsor_type is null or s.sponsor_type like '%Duke%' or s.sponsor_type like '%Other%')</td>
</tr>
</tbody>
</table>

6.4 Data Definitions

The Data Definitions page provides additional information on the data contained within the dashboard. As shown below, information is provided for each of the chart sections (Enrollment Trend, Demographics, and Funding Source) of the dashboard.
Figure 19. Duke Enrollment Dashboard – Data Definitions

7 Revision Record

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<th>Created By</th>
<th>Change Notes</th>
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<td>1.0</td>
<td>3/17/2016</td>
<td>Matt Schultz</td>
<td>Updated to include Tier III information</td>
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