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What is the OnCore Enterprise Research System?

OnCore stands for Online Collaborative Research Environment. It is a Clinical Trial Management System (CTMS) developed by Forte Research Systems that supports academic medical centers, cancer centers, and healthcare systems around the country. OnCore has been purchased by the University at Buffalo to support research activities and compliance, which will allow for enhanced trial management, robust reporting, enrollment tracking, and accurate clinical research billing.

Integration between OnCore and the Click portal will ensure that protocols submitted and reviewed by the IRB within Click are seamlessly transitioned to the OnCore system. The combined systems will manage the entire lifecycle of a research project, from protocol creation to project closeout.
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Major Components of OnCore

Most of OnCore’s functionality centers around a Protocol. Researchers typically want to enter information about their protocols and register subjects to their protocols. It can be useful to track the institutions that are participating in a study, the staff assigned to each protocol, the protocol calendar, and other information relevant to the Research Center. This might include drugs being tested during a study, whether a study is local or national, whether adults and/or children will participate, etc.

Libraries

Libraries are a set of forms, reference codes (option settings), protocol annotations, notifications, and sign offs. When a protocol is created in OnCore, a Library is assigned to the protocol, which ensures every user viewing or working on that protocol will use the same information.
Institutions

Institutions are the logical business units of clinical trials, generally the hospitals or clinics that participate in a protocol. OnCore recognizes five different institution types:

Office of Clinical Trials (OCT) – The Office of Clinical Trials is the administrative side of the Research Center. OCT Staff can see subjects from all institutions that are registered on protocols to which they have access. UB’s Clinical Research Office (CRO) will function as the OCT.

Research Center - The Research Center is the ‘parent’ institution, and usually hosts the OnCore software. The University at Buffalo (UB) will function as the Research Center. Staff registered to this level can access protocols and subjects assigned to the Research Center – but they do not have access to subjects enrolled at Affiliates, Consortium Members, or the VA.

Affiliate - An Affiliate Institution can be considered a ‘child’ institution of the University. Typically Affiliate Institutions have their own IRB. Affiliate staff will only have access to protocols and subjects that have been assigned to their institution and its study sites. An Affiliate can have multiple Study Sites – locations where patients are seen. Roswell Park Cancer Institute is considered an Affiliate Institution.

Consortium Member – A Consortium Member Institution has the same properties as an Affiliate. Consortium Member Institutions differ from Affiliates in that their accrual is considered University at Buffalo accrual. They also typically utilize UB’s IRB. The Erie County Medical Center (ECMC), Kaleida Health, and UBMD are all Consortium Member Institutions.

VA - A VA Institution is functionally identical to an Affiliate, with the exception that only one institution may be designated a VA. The VA WNY Healthcare System will function as our VA.
Access Roles

An **Access Role** is a set of privileges that determines the pages, tools, and information that a user can see in **OnCore** – limiting an institution’s staff members’ access to only appropriate protocols and subjects.

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Administrator (Admin)</strong></td>
<td>Responsible for the upkeep, configuration, and reliable operation of the OnCore Enterprise Research system. This may include troubleshooting reported problems, updating system software, and tasks such as creating user accounts and uploading relevant documents.</td>
</tr>
<tr>
<td><strong>Bio-Statistician (ST)</strong></td>
<td>Develops, improves, and applies rigorous statistical methods that enhance the quality of research. Provides the statistical methodology for the assessment of the primary objectives of the research.</td>
</tr>
<tr>
<td><strong>Clinical Research Coordinator (CRA)</strong></td>
<td>Handles most of the administrative responsibilities of a clinical trial; acts as liaison between investigative site and sponsor and reviews all data and records before a monitor’s visit.</td>
</tr>
<tr>
<td><strong>Data Monitor (DM)</strong></td>
<td>Examines case report forms for completeness, consistency, legibility, and accuracy.</td>
</tr>
<tr>
<td><strong>Executive Oversight (EO)</strong></td>
<td>Monitors human subject safety by reviewing and evaluating the accumulated study data, reviews study conduct and progress, and makes recommendations concerning the continuation, modification, or termination of the study.</td>
</tr>
<tr>
<td><strong>Financial Coordinator (FC)</strong></td>
<td>Coordinates, administers, and oversees the research finance and billing compliance for clinical trials. Ensures accurate billing for clinical trial participants in accordance with federal regulations to maintain institutional compliance, and reduce financial and legal risk.</td>
</tr>
<tr>
<td><strong>Role</strong></td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hospital Billing Coordinator (HOS)</td>
<td>Compiles data, computes fees and charges, and prepares invoices for billing purposes at an institution.</td>
</tr>
<tr>
<td>Investigator (PI)</td>
<td>Responsible and accountable for conducting the clinical trial or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. The Principal Investigator (PI) assumes full responsibility for the treatment and evaluation of human subjects, and for the integrity of the research data and results.</td>
</tr>
<tr>
<td>Protocol Coordinator (PC)</td>
<td>Creates a protocol in OnCore, ensures the protocol data is correct (e.g., title, staff, sponsor, protocol status, etc.), and updates the protocol as necessary.</td>
</tr>
<tr>
<td>Regulatory Coordinator (REG)</td>
<td>Assures that clinical research is compliant with applicable state, federal, and/or international requirements, while adhering to policies of the University at Buffalo and other institutions involved in research. Provides support for protocols to include study start up activities and maintenance of regulatory records throughout the life of each protocol.</td>
</tr>
</tbody>
</table>
Calendars

Protocol Calendars

To track subject visits or financial information for a protocol, the protocol must have a calendar attached to it. A Protocol Calendar is a schedule of subject treatment visits, a list of what will be done during each subject visit, a designation of the data to be captured, and the forms used to record the data. Protocol Calendars use generic milestone dates (e.g., the day the subject signs the consent form) to create a nonspecific schedule. The Protocol Calendar serves as the blueprint for subject tracking.
Subject Calendars

A Subject is a person that has been enrolled on a protocol. Once the subject has consented and is put on study, a personalized Subject Calendar with specific dates for that patient is generated. It serves as a personalized visit schedule for the subject.

Electronic Case Report Forms (eCRFs)

Clinical users will be able to enter data on subject forms for each subject visit, as appropriate. Form templates built in OnCore are known as eCRFs (electronic Case Report Forms).

Charge Master

A universal Charge Master can be used to list standard costs for procedures that can be performed at the institution and its affiliates – it is a repository of administrative and clinical events associated with clinical research (e.g., protocol start-up costs, IRB fees, procedures, etc.) and each event’s associated charges.
Navigating in OnCore

Tips for Successful Navigation

Use only one instance of OnCore at a time

Only one session (browser window or browser tab) of the OnCore Enterprise Research system website should be open at a time on your computer. Multiple sessions of OnCore could result in duplicate data and application misbehavior.

Use a computer with a keyboard and a mouse

OnCore stores large volumes of complex information about the protocols, subjects, calendars, and budgets in your research portfolio. When using the application, use a keyboard and a mouse for efficient data entry. Using a tablet or a touchscreen can make data entry feel cumbersome or time-consuming, while using a keyboard and mouse can speed up your workflows significantly.

Avoid using the browser’s back button

Use OnCore’s buttons, tabs, and menus to navigate within the program; do not use the browser’s navigation buttons. Using the browser toolbar to navigate might lead to unexpected results, such as unsaved data or webpage errors.

Single-click buttons and links

Especially when clicking Save or Submit to create a new record, click once so that only one record is created and duplicate data is not saved in the database. Avoid double-clicking the mouse when working in OnCore.

Disable pop-up blockers on your web browser

OnCore uses many pop-up windows that allow you to make selections and enter data. If your browser is set to prevent pop-up windows from opening, it will also prevent OnCore’s pop-up windows from opening.
You must allow pop-up windows to open in each browser that you are using with OnCore:

- To allow pop-up windows in **Chrome**, select the ‘Always allow pop-ups’ option:

![Chrome pop-up settings](image1)

- To allow pop-up windows in **Firefox**, select the ‘Allow pop-ups’ option:

![Firefox pop-up settings](image2)

- To allow pop-up windows in **Internet Explorer**, select the ‘Always allow’ option:

![Internet Explorer pop-up settings](image3)
To allow pop-up windows in **Safari**, use the **Command-Shift-K** keys to toggle it on or off.

---

**Supported Browsers**

<table>
<thead>
<tr>
<th>Browser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chrome</td>
</tr>
<tr>
<td>Firefox</td>
</tr>
<tr>
<td>Internet Explorer 9, 10, and 11</td>
</tr>
<tr>
<td>Safari</td>
</tr>
</tbody>
</table>
Logging into OnCore

1. Navigate to http://ctms.buffalo.edu
2. Locate the Login area.
3. Enter your UBIT Name and click the Next button.
4. Enter your Password in the field, and then click the Login button.

**NOTE:** Faculty and staff users will log into the system using their UBIT Name and Password.

Requesting an Account

Accounts have been created for faculty and staff at the University at Buffalo via the Click Portal. If your login to OnCore is unsuccessful, or if you are a student participating on a research team, please follow the instructions below to request an account:

1. Navigate to the Click Portal: IRB and Managing Compliance page at http://www.buffalo.edu/research/research-services/compliance/irb/click-irb.html
2. Locate the Click Portal Login area at the top-right of the page, and click on the registration link.
3. Complete the Request Account form at the bottom of the page, and then click the Register button. Be sure to select the University at Buffalo as your Campus Affiliation.

You will receive an email notification when your account has been activated.
Home Page

Each time you log into the OnCore Enterprise Research System, you will be taken to the Home Page. This area, also known as the dashboard, contains the OnCore Menu Bar, which provides quick links to various areas of the site. The area underneath the Menu Bar is fully customizable and can be modified to provide quick access to frequently-used elements in the system.

The OnCore Menu Bar

The Menu Bar at the top of every page provides quick links to OnCore tools, as well as information about the current user.

1. Clicking the OnCore Logo returns you to the Home Page from anywhere in OnCore.
2. The Main Menu contains all menus and menu items that you have permission to see.
3. The Favorites Bar appears under the header. It contains menus and menu items that you have permission to see.
4. The Environment Name shows what environment you are working in. For example, if you are in the training environment that has been set up for you to practice in, that label may say oncore – train.
Current User shows the name of the user that is currently logged into OnCore.

The gear icon (⚙️) – located directly beneath the Current User - opens the Home Screen Configuration page, allowing you to select Widgets. They provide quick access to your protocols, subjects, saved searches, or other frequently used tools.

Personalizing Your Home Page

The Favorites Bar

All of the menus and tools that you have access to appear under the Main Menu.

1. Click the Menu option in the Toolbar.

2. Click the star icon (⭐️) next to any category or tool to add it to your Favorites Bar.
3. Once the menu items are placed on your **Favorites Bar**, use drag-and-drop to rearrange them as necessary.

![Image of rearranging menus](image)

The User Menu

The **User Menu** provides links to your **Home Page**, your **User Profile**, and custom **Help** links such as the **Learning Portal**, **Onsemble.net**, and UB’s customized materials for **OnCore**.

1. Click the drop-down arrow next to your name to open the **User Menu**.

   - **User Profile** – Contains general information about your account, such as username, first and last names, etc. Clicking the **Edit** button allows you to update your **Title** and **Contact Numbers**.

   - **Effort Tracking** – From here, you can record the amount of time you have spent on protocol-related tasks. Not currently being implemented at UB.

   - **Show PHI** – Dependent on your account permissions, this allows you to temporarily show/hide **Protected Health Information (PHI)** to prevent that information from being visible to people not authorized to see it.

   - **Help** – Provides links to the Learning Portal, the OnCore Training site, and the OnCore Implementation site.
• **About** – Provides information regarding the version of **OnCore Modules** we are currently using.

• **Home Page** – Returns you to the **Home Page**.

• **Queued Tasks** - Allows you to view the progress of tasks like reports and data imports. The number of tasks processed but not yet viewed in **Queued Tasks** appears next to the **Queued Tasks** menu item in the user menu and next to your username. The number next to the **Queued Tasks** menu item also indicates whether the task was successful or not: **green** for successful and **red** for unsuccessful.

• **Logout** – Logs you out of the **OnCore Enterprise Research System**.

### Adding Widgets

The **Home Page** can include a variety of widgets. A **Widget** is a personalized list of **OnCore** data; widgets provide quick access to frequently-used elements in **OnCore**, such as protocols, subjects, and reports. Users can choose the widgets that appear on their Home screen and configure the records and fields that display in the widgets.
1. Click the gear icon (⚙️), located directly beneath the **Current User**.

Any **Widgets** that have already been added to the **Home Page** are shown in the **column 1** and **column 2** boxes at the top of the **Home Screen Configuration** page. **Widgets** that can be added to your **Home Page** are listed at the bottom of the page.

The available **Widgets** are:

<table>
<thead>
<tr>
<th>Widget Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active Tasks</strong></td>
<td>Lists all of your incomplete tasks that have a Target Date</td>
</tr>
<tr>
<td><strong>Protocols</strong></td>
<td>Displays summary protocol information.</td>
</tr>
<tr>
<td><strong>Reports</strong></td>
<td>Lists the most recently accessed reports.</td>
</tr>
<tr>
<td><strong>SAEs</strong></td>
<td>Displays Serious Adverse Event (SAE) information.</td>
</tr>
<tr>
<td><strong>Saved Searches</strong></td>
<td>Displays saved protocol and subject searches.</td>
</tr>
<tr>
<td><strong>Subjects</strong></td>
<td>Displays subject information.</td>
</tr>
<tr>
<td><strong>Upcoming Tasks</strong></td>
<td>Displays upcoming tasks assigned to a user by name or role.</td>
</tr>
</tbody>
</table>

2. Select the **Add** checkboxes for the desired **Widgets**.

3. Click **Save**. The page will redraw, and the selected **Widgets** will appear in **column 1** and **column 2**.

   - To move a **Widget**, click it and use the **green arrows** to move it up or down, or to a different column. Then click the **Save** button.

   - To remove a **Widget**, click it and then click the **Delete** button.

4. Click **Home** in the **Toolbar** to see how the **Widgets** are placed on the **Home** screen.
Configuring Widgets

Once widgets have been added to the Home Page, they must be configured before they begin showing information. To allow you to configure the widget according to your individual needs, each widget has one or more of these tabs:

- **Watch** - Configures which records are being ‘watched’ and will appear in the widget.

- **Fields** - Lists the fields that are shown in the Dashboard view (on the Home Screen) and in the Expanded view (when the expand icon is clicked).

- **Bookmarks [Protocol]** - Shows the protocols that have been bookmarked. When viewing a protocol in the PC Console, you can bookmark it by clicking on the star symbol in the upper-left corner. The bookmark for a protocol can be removed via the PC Console, or via the Protocol Widget.

- **Bookmarks [Subject]** - Shows the subjects that have been bookmarked. When viewing a subject in the Subject Console, you can bookmark it by clicking on the star symbol in the upper-left corner. The bookmark for a subject can be removed via the Subject Console, or via the Subject Widget.

1. If a Widget is configurable, a **gear icon** will appear in the top-right corner of the Widget. Click the **gear icon** to begin.

   **NOTE:** The Reports and Saved Searches Widgets are not configurable.

2. Use the tools on each available tab to control settings:
- **Watch** – Use the Yes/No dropdown menus to determine whether or not information will be displayed for a **Widget**. Some **Widgets** may also include checkboxes to select appropriate roles.

- **Fields** – Use the checkboxes underneath the **Dashboard** (Home Page) and **Expanded** columns to determine which fields will display for those areas. You may also determine the maximum records that will display for a **Widget** at the bottom of each column.

- **Bookmarks** – These tabs will show [Protocols] or [Subjects] that have been bookmarked. Once these items have been bookmarked, use the checkboxes here to remove them, if needed.

3. Click **Save**.

   **Note:** If you are a new user and do not have anything bookmarked at this point your **Widgets** may not immediately populate with information. They will not do so until you have bookmarked some items within the system.

### Bookmark a Protocol

1. Click **Menu** in the Menu Bar, and then navigate to the **Protocols** menu, and select **PC Console**.

   **Note:** In OnCore, the action of moving through several options to reach a desired location is called **navigation**. For convenience, navigation through several areas of a function is often described in a **path**, such as **Menu > Protocols > PC Console**.

2. In the **Select Protocol** field, enter a search term OR click the arrow on drop-down menu to locate a protocol.
3. The protocol information will appear in the **PC Console** window. Click the **star icon** in the **PC Console header** to bookmark the protocol.

4. Click the **OnCore Logo** in the **Menu Bar** to return to your **Home Page**.

Now some of your **Widgets** may now have links. This allows you to quickly jump to any item that you have bookmarked.
Consoles

OnCore contains several consoles. A Console is a set of related pages for a particular workflow, function, or type of data. For example, the PC Console displays information about one protocol at a time: the protocol number and title, the type of study, the staff assigned to the protocol, the protocol sponsor, and other protocol-related information.

To explore the elements of a console:


The PC Console opens, allowing you to select a protocol.

2. All protocols in OnCore are identified by an alphanumeric Protocol Number. Select a protocol by entering a search term (e.g., the Protocol Number or Title) in the Select Protocol field.
3. From the search results, click on the Name of the protocol you wish to open.

4. The PC Console will include the Protocol Number and Title, the Type of study, the Staff assigned, the Sponsor, and other related information.

In the same way, the Subject Console (Menu>Subjects>Subject Console) displays information about a selected subject. It also provides tools where you can update demographic information, document consent, or view the Subject Calendar.

Find-As-You-Type Fields

The Select Protocol field is a find-as-you-type field. Typing an entry in this field prompts OnCore to immediately display a list of potential protocols as soon as it
matches a part of your entry. This field can be used to help you locate your protocol by limiting the number of potential matches.

For example, if you type 12 in this field, OnCore will immediately display a scrolling list of all protocols containing 12 as part of its Protocol Number.

**NOTE:** The following terms may be used to search for a protocol within OnCore:

- **Protocol Number** - You can search based on the Protocol Number, or any of the following alternate numbers: IRB/SRC/Pharmacy/Sponsor/GCRC/IND/IDE/Contract/NCT.

- **Keyword** - Matches protocols having the supplied value in the protocol Title, Short Title, or Objective fields.

- **Investigator** - Matches protocols having the specified staff name assigned as Principal Investigator on the Protocol Staff page.

- **Institution** - Matches protocols having the specified institution as a Participating Institution.

**Console Header**

The **Console Header** provides at-a-glance information about the selected record (such as the protocol, subject, or calendar, and so on) within any console in OnCore. In the example below, the PC Console shows the Protocol Number, Sponsor, Principal Investigator, Status, and Accrual information for a particular protocol.

Click the star icon to bookmark the protocol.

Click the ? for OnCore Help and documentation.
Vertical tabs

Along the left side of the **PC Console** is a column of vertical tabs. **Vertical Tabs** allow you to enter and view information specific to the area described by the tab. For example, the **Treatment** tab allows you to view the protocol’s treatment steps and arms.

Horizontal tabs

Some vertical tabs in **OnCore** are further organized into horizontal tabs. **Horizontal Tabs** allow for easy navigation between subsets of the information contained on the selected vertical tab.

A quick way to access the horizontal tabs is to click on the >> arrows on a selected vertical tab, which will display a drop-down list of options identical to the horizontal
tabs. Selecting the option from the drop-down list allows you to navigate directly to one of the horizontal tabs.

In the example below, the Main vertical tab contains an additional 6 horizontal tabs: Details, Management, Staff, Sponsor, IND/IDE, and ClinicalTrials.gov/CTRP.

The horizontal tabs can also be found under the >> arrows on some of the vertical tabs.

View-Only Mode vs. Update Mode

Many pages in OnCore display in View-Only or Update Mode. In View-Only Mode, you can view data but you cannot make modifications to it. In Update Mode, the fields on the page become editable, and radio buttons and checkboxes become selectable, allowing you to make modifications to the data.

The ability to view or update data in OnCore is controlled by assigned privileges. In most cases, one privilege will grant read-only access to a screen in OnCore, and an additional privilege must be granted in order to update data on that screen.

If you have the privilege to update information on a screen in OnCore, an Update button will appear in the lower-right corner of the page. In Update Mode, you can edit data in text fields, select different values from the drop-down menus, and select or deselect options on a page.
Once you are in Update Mode, several additional buttons appear at the bottom of the page. These buttons typically include the Submit, Clear, and Close buttons.

- **Submit**: Saves the data entered on the page; the page remains in Update Mode.
- **Clear**: Restores all fields to their most recently saved values; it does not erase all data on the page.
- **Close**: Returns the page to View-Only Mode; any unsaved data will be discarded.

**Add Blocks**

Some OnCore pages contain Add Blocks, which are sections on the page that allow you to update a subset of the data contained on that page. Add Blocks contain their own set of New, Update, Clear, Close, and Submit buttons.
In the example that follows, after selecting a role and a staff person, you must click **Add** to assign the staff member to a protocol:

![Add button](image)

The **Clear** and **Close** buttons on the **Staff** tab are specific to this **Add Block**:

- Click **Clear** to remove the selections.
- Click **Close** to return to **View-only Mode**.

**Date Widgets**

Fields that have the **Date** icon to the right of the field display date widgets. Clicking on the **Date** icon launches the **Date Widget**, where you can select your date from the **Date Widget Calendar**.
**OnCore** accepts dates in a number of formats, including 1 or 2-digit months and days and 2 or 4-digit years. **OnCore** converts all entries into the MM/DD/YYYY date format. If you enter two-digit months and days, you can omit the slashes. Any of the following are acceptable:

- 12/2/09 will become 12/02/2009
- 09/01/1955 is accepted as-is
- 4/6/88 will become 04/06/1988
- 080810 will become 08/08/2010

*Date* fields in **OnCore** also accept a variety of *keyboard shortcuts*, or dates that are calculated relative to another date, as opposed to a specific date.

<table>
<thead>
<tr>
<th>Shortcut</th>
<th>Resulting entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>t</td>
<td>Inserts the current date</td>
</tr>
<tr>
<td>t + n</td>
<td>Inserts a date n days from today:</td>
</tr>
<tr>
<td>t - n</td>
<td>(where n is a number)</td>
</tr>
<tr>
<td>t +3</td>
<td>t +3 is three days from today</td>
</tr>
<tr>
<td>t-1</td>
<td>t-1 inserts yesterday's date (1 day ago)</td>
</tr>
<tr>
<td>w – n</td>
<td>Inserts the current date plus/minus n number of weeks</td>
</tr>
<tr>
<td>w + n</td>
<td>w – 6 will insert a date 6 weeks ago</td>
</tr>
<tr>
<td>w + 2</td>
<td>w + 2 will insert a date 2 weeks from today</td>
</tr>
<tr>
<td>m + n</td>
<td>m + n inserts the current date plus/minus n number of months</td>
</tr>
<tr>
<td>m – n</td>
<td>m – n</td>
</tr>
<tr>
<td>y + n</td>
<td>y + n inserts the current date plus/minus n number of years</td>
</tr>
<tr>
<td>y – n</td>
<td>y – n</td>
</tr>
<tr>
<td>mb or me</td>
<td>Inserts the beginning or end of the month respectively; it can be used alone, or with + or – with a number</td>
</tr>
<tr>
<td>yb or ye</td>
<td>Inserts the beginning or end of the year, respectively; it can be used alone or with + or – with a number</td>
</tr>
</tbody>
</table>
**Note:** When entering a keyboard shortcut into a Date Widget field, you can press Enter, Tab, or click anywhere outside the Date Widget to calculate the appropriate date in MM/DD/YYYY format.