Using CITI Program Content: An Introduction

CONTENT AUTHOR

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INTRODUCTION

CITI Program educational materials are highly customizable. Our "core" content can be assembled to fit the specific needs of your organization's learners; and it can be supplemented with custom content that you develop exclusively for your organization. CITI Program content is designed to be a component of an overall foundation of training for an organization's affiliates. We recommend that organizations build frameworks of training that combine CITI Program content with face-to-face training, one-on-one mentoring, and other types of learning opportunities, as appropriate to the particular topics and their organizational cultures.

Making good use of this flexibility requires that you understand the structure of CITI Program's educational materials, and have a basic familiarity with the capabilities of the CITI Program web platform to deliver content. This document provides an overview that applies to all CITI Program materials.

LEARNING OBJECTIVES

By the end of this module, you should be able to:

- Understand the structure of CITI Program's educational content, and how it can be customized to meet the needs of your organization's learner groups.
- Understand how learners interact with the CITI Program web platform to configure their menus of courses, and how they work through course content assigned to them.
- Understand the types of reports the CITI Program web platform makes available to each learner, and the reports for you or your organization to track all your affiliated learners' progress.

CITI PROGRAM'S CONTENT SERIES

CITI Program's educational content is grouped into subject areas, generally referred to as content **series**. The current series include:

- Animal Care and Use (ACU)
- Biosafety and Biosecurity (BSS)
- Clinical Research Coordinator (CRC)
- Clinical Trial Billing Compliance (CTBC)
- Conflicts of Interest (COI)
- Disaster Planning for the Research Enterprise (DPRE)
- Essentials of Research Administration
- Export Compliance (EC)
- Good Clinical Practice (GCP)
- Good Laboratory Practice (GLP)
- Healthcare Ethics Committee (HEC)
- Human Subjects Research (HSR)
- Information Privacy and Security (IPS)
- IRB Administration
- Responsible Conduct of Research (RCR)

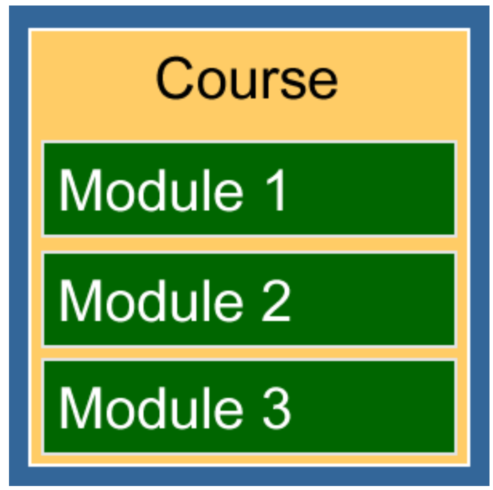
In some cases these series are further sub-divided, to cluster content according to subject matter, disciplinary audience, or regulatory focus. For example, the HSR series has course **tracks** focused on biomedical research, as well as content oriented to social-behavioral-educational research. The GCP series has separate courses specific to regulatory requirements and considerations for clinical trials of drugs, biologics, and devices.

CITI Program's **content catalogs** and **series selection forms** make suggestions about assembling courses that fit common needs. However, it is possible to mix and match content from any series in CITI Program's library to create customized courses for your learners. For the complete current listing of content, visit citiprogram.org.

MODULES, COURSES, AND COURSE-STAGES

At the most basic level, CITI Program content is organized into **modules**, which can be thought of as the lessons that make up a **course**. Modules are composed of text and images, and may include supplemental materials such as case studies or videos. That content generally follows a standard format, similar to what you are now reading. It begins with an introduction of the topic(s) to be covered, then provides a set of learning objectives; after that comes the main material, broken up into sections, followed by a concluding summary section. References and any recommended supplemental materials complete the package. Modules are generally length-restricted so as to require at most approximately 20 minutes for the average learner to complete. (In addition to its title, each module has a unique **module-ID** number, which you will see in the content catalogs and in various other forms.)

Modules typically include a **quiz** made up of multiple-choice questions. Achieving a cumulative average passing score on the entire set of required quiz questions is necessary to “complete and pass” the course. (Organizations can also optionally set a per-module minimum quiz score, which is enforced along with the average score requirement.) When a learner completes a quiz, feedback is usually provided for each question, which includes guidance on why the answer selected was correct or incorrect. Learners can revisit module content, and quizzes can be retaken to achieve a higher score until a desired result is achieved. (Usually, each quiz has questions randomly selected from a larger bank of questions, so the quiz will not be an exact repeat.) Learners complete modules that do not require a quiz, such as for a course overview that introduces the material, simply by opening the module for reading.



For a **course**, modules may be set as **required** (the learner must complete all of them, typically in a prescribed order); or they may be set as **elective** (the learner must complete a minimum number of a group of modules, in whatever order the learner chooses). **Supplemental** modules may also be provided as part of a course, which the learners may access (at their discretion) after completing the required and elective modules. These do not affect the overall passing score nor do they count towards course completion. We can recommend additional modules that may be of interest to a learner given the topic; but, as with all other content, the inclusion or exclusion of supplemental modules is at the organization’s discretion.

For each set of modules that has been assembled into a course, a learner has an associated **gradebook**. The gradebook shows the learner’s progress for each module of that course – not yet started, started but not completed, completed and passed, or completed but not yet passed – and also shows both individual and average scores on quizzes taken up to that point. The number of required and elective modules still pending is also noted.

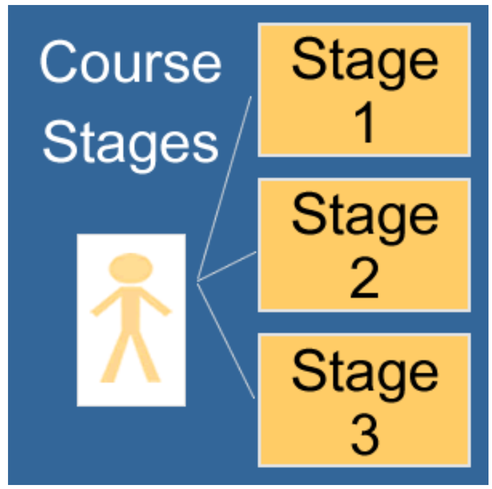
Each module is “completed” by completing its quiz (unless there isn’t one). A course is deemed “completed and passed” when all its required modules (and a minimum number of its elective modules, if any) have been completed, and the average score on all quizzes exceeds a minimum-passing grade. The required average passing score can be set at any level the subscriber organization wishes – the default is usually 70 to 80 percent. (As noted, if a per-module minimum score has been set, this is also enforced as a part of determining what has been passed.)

How are courses assigned to individual learners?

We work with each subscriber organization to define a set of one or more **learner groups**. Each learner group corresponds to a sub-population of the organization's learners with unique content needs.

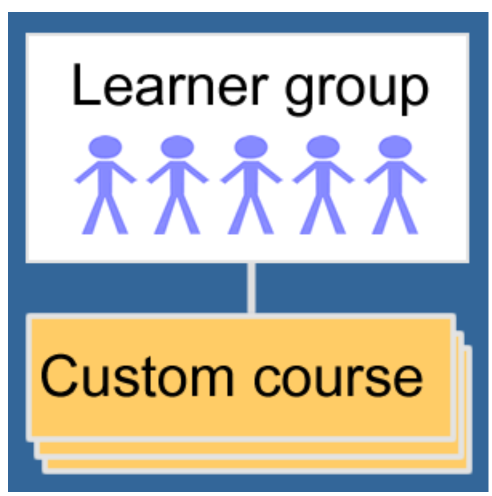
How are individual learners assigned to learner groups?

Access to CITI Program's web platform requires assignment of a unique username and password for each learner. (Organizations using Single-Sign-On [SSO] rely on the unique usernames and passwords already assigned for their affiliates' work.) As part of the registration process to create a CITI Program account, a learner is asked a set of questions that identifies the organization, and the learner group(s) of that organization, to which he or she belongs. We work with each subscriber organization to construct this customized set of questions. (Some learners are affiliated with more than one CITI Program subscriber organization, in which case they are asked learner-group-assignment questions for each affiliation separately.) Learners can update answers to these questions at any time if their learning needs change by clicking on an "update institution profile" link.



Assignment to a learner group automatically determines the set of courses presented to a learner. As noted, for each assigned course there is a separate gradebook.

CITI Program's web platform allows all of a learner's assigned courses to be presented at the same time; or the courses can be presented over defined intervals in what the CITI Program platform calls **stages**. For example, HSR training typically requires renewing (refreshing) every few years. We can structure an initial course, typically called a **basic course**, for presentation immediately as stage 1; and then schedule a **refresher course** at a later date as stage 2; and then another refresher at a defined interval after that as stage 3; and so on. The time between completing a stage and when the next course is due is called the stage's **expiration period**. Expiration periods are determined by the organization for each learner group's designated courses when the content set is configured. (Organization policies most often determine these durations, but choices may also be conditioned by regulatory requirements.) An automated email message notifies learners that the next stage of a course is due. (For this reason, it is important that learner's profiles are kept up to date, at least with respect to email addresses.)



LEARNER PROGRESS REPORTS

Once all the required modules in a course have been completed and passed, along with a sufficient number of elective modules (if any), the course **completion report** is made available to both the learner and to a subscriber organization's designated **administrators**. Completion reports have two parts:

1. The first part lists only the required elements of the course, including the quiz scores at the moment the requirements were met.
2. The second part is a continually updated listing that includes any new quiz scores as well as any supplemental modules the learner may have taken.

Learners can print their course completion reports as needed. Organizational administrators can receive report notifications in daily emails (one for each learner's completion in a particular learner group); reports can also be created ad hoc as needed, using administrator tools; or we can schedule automated downloads of completion report details for all affiliated learners of a particular learner group. (An administrator's reports are generally clustered by learner group. We work with each subscriber organization to set up an appropriate set of data values, the learner-groupings and frequency of reporting.)

Though every member of a learner group is presented with the same content, and included in group reports of completions for that set, his or her individual progress is individually tracked and individually reportable.

INFORMATION IN LEARNERS' PROFILES

As noted, access to CITI Program content requires an individually-assigned username and password, assigned during the initial user registration process (or by the organization, if using organizational credentials via SSO). During registration, a new CITI Program user must respond to a series of "demographic" questions, including name and contact information. (This step is usually skipped in SSO implementations.) These data form the basis of the user's **CITI Program profile** (sometimes called the "global profile"). A profile includes, critically, the user's primary email address, and an optional alternate email address in case the primary address is not available. These addresses are used for administrative transactions, the most important of which is assisting a learner when the username or password is forgotten.

For each CITI Program subscriber organization with which the user is affiliated, the learner has an **organization profile**. We can ask for additional demographic information (such as an specific ID number or email address) as part of assembling this profile, which will assist you in identifying a particular learner's records. After providing this demographic information, responses to customized enrollment questions allow sorting of the learner into one or more learner groups as described above. For each subscribing organization with which the learner is affiliated, there is at least one concomitant course (and associated course modules) for each learner grouping. Learners' responses to the organization's enrollment questions determine the learner group (course) assignments.

Learners may update both their global profiles and organization profiles at any time. Learners who are affiliated with more than one organization may add new organization profiles at any time (or deactivate affiliations that are no longer valid).

CUSTOMIZED ORGANIZATIONAL INFORMATION

While the CITI Program's Help Desk staff can assist learners with general questions about the CITI platform, they cannot provide information about organization-specific policies or procedures. **Subscriber organizations are strongly encouraged to provide basic contact information to assist their affiliated learners in finding persons who can answer such "local" questions.**

This information is included on an **institutional contact page,** which is accessible to the learner via a link in the "My Learner Tools" section of the Main Menu. This content of this page should include contact information for one or more persons who manage CITI Program training at the organization.

Typically, the institutional contact page also includes administrative contacts relevant to the content series that the learner has selected, such as:

- Export Control/Compliance department (if using EC content)
- Institutional Animal Care and Use Committee (ACU)
- Institutional Review Board or Research Ethics Committee (GCP, HSR, or IRB Administration)
- Laboratory Safety Committee or Institutional Biosafety Committee (BSS)
- Privacy/Security Officer or HIPAA enforcement department (IPS)
- Research Integrity Officer or Research Compliance department (RCR)

CUSTOMIZED ORGANIZATIONAL INSTRUCTIONS

Organizations may also optionally provide a customized **institutional instruction page** to guide their learners' use of CITI Program content (for example, to provide special instructions about how learners report their completions). This page is also accessed via a link in the "My Learner Tools" section of the Main Menu. If content for this page is not provided, we use a standard generic set of instructions.

CUSTOMIZED ORGANIZATIONAL MODULES

Subscriber organizations can also write their own **custom modules** for addition to the CITI Program library. These custom modules can be integrated into any of the organization's courses. This custom content is accessible only to the affiliates of the organization who are accessing such courses.

There is a per-hour service charge for editing and formatting organization-generated content into modules; typically this requires a few hours of technical service time. Note also that organizations are entirely responsible for keeping the content of their customized modules accurate, up to date, and compliant with legal requirements such as copyright clearance and ADA/508 accessibility. CITI Program does not review the content of custom modules, and takes no responsibility for their content.

U.S. subscribing organizations may not customize the U.S. CITI Program core modules. The standard versions must be used.

CUSTOMIZED REPORTS: AUTOMATIC AND ON-DEMAND

As noted, CITI Program's software can generate and send (via email) completion reports to select subscriber organization administrators, customized at the learner group level. Designated administrators can also generate their own reports from the CITI Program's website as needed, using the administrator tools. Alternatively, we can set up automated downloads directly to an organizational server. Download file security is provided via encryption and other mechanisms.

CUSTOMIZED LOGIN CREDENTIALS

CITI Program's site can be configured to use an organization's own user-ID and password credentials for authentication, rather than a user-ID and password combination that is unique to CITI. We call this service "Single-Sign-On (SSO)" or "portal authentication." CITI SSO uses the industry-standard Shibboleth protocol. There is a one-time fee for SSO setup. Organizations that are members of InCommon qualify for a discounted SSO implementation rate.

AVAILABLE CONTENT LANGUAGES

Some CITI Program modules are available in more than one language, including English, French, Khmer, Korean, Mandarin Chinese, Portuguese, Russian, Spanish, Tamil, Thai, and Vietnamese. Almost all content is available in English; Spanish is the most common alternative to English. See the CITI Program content catalogs for current availability. **If your organization requires translation of a particular module into a new language, we can arrange for that, but there will be an associated fee.**

CONTINUING EDUCATION CREDIT: CMEs and OTHER CEUs

Many of CITI Program's modules are approved for Continuing Education Unit (CEU) credit. This includes Continuing Medical Education credit (CMEs, specifically *AMA PRA Category 1* ™), as well as credit for physicians, psychologists, nurses, social workers, and other professions. See the CITI Program content catalogs for availability or visit the CE Information page.

SPECIFYING YOUR ADMINISTRATORS

Every CITI Program subscriber organization must have at least one administrator who decides on the configuration of learner groups and associated content, registration questions, profile variables, and so on. CITI Program's platform allows designation of multiple administrators, each with an assigned privilege level. Basic-level administrator privileges allow generation of reports on learner progress. Administrators with mid- and high-level privileges can request changes to course configurations, learner groups, etc., via the CITI Program's Help Desk. We strongly recommend that you limit the number of persons with mid- and high-level privileges.

SUMMARY

CITI Program's content library and web platform allow you to customize content to meet the needs of learners at your organization. Because CITI Program's content is extensive, it requires a bit of work up front to determine the appropriate configuration of modules and courses for your organization's audiences. Our Help Desk staff members are experienced with all of CITI's content series, and can assist you with that task. Contact them at citisupport@med.miami.edu or 888-529-5929.

ACKNOWLEDGEMENTS

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RELATED DOCUMENTS

- Using CITI Program Content: Animal Care and Use (ACU)
- Using CITI Program Content: Clinical Research Coordinator (CRC)
- Using CITI Program Content: Clinical Trial Billing Compliance (CTBC)
- Using CITI Program Content: Conflicts of Interest (COI)
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To download these documents, visit the CITI Program homepage at citiprogram.org and click on the "Courses" tab. Each document will be listed within its respective series or course listing.

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