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V. MCC Welcome Guide Overview

This welcome guide provides helpful information to new MCC members. Now that your organization is a MCC Member, you are invited to set up individual user accounts, sign-up to participate in online work groups and access MCC Metric Sets, Tools and Training Webinars. This guide will provide you with step-by-step descriptions of how to get started!

If your organization is not a MCC member, please visit the MCC website to download the “How to Apply for MCC Membership Guide” for details. If further information is needed, contact the MCC Membership Coordinator, Terry Holland at 317.622.0266 ext. 108 or tholland@metricschampion.org.

VI. MCC’s Mission & History

Founded in 2006, MCC is the leading industry association dedicated to the development of standardized performance metrics to improve clinical trials. MCC provides the collaborative environment for biopharmaceutical and device sponsors, service providers and sites to improve clinical trial development through the adoption and use of MCC standardized performance metrics [see MCC At-A-Glance for summary].

VII. Value of MCC Membership to Your Organization

Over the past several years, Metrics Champion Consortium (MCC) has worked to develop many new and innovative products and services to benefit you and your organization. We are committed to continuing these efforts. Recently, we updated the MCC public website, Member Portal and e-commerce area to create a more user-friendly experience. The News Blog keeps you informed of specific MCC initiatives and links to our White Papers. We invite you to visit www.metricschampion.org to view the enhancements, and to access helpful documentation and information about MCC such as:

- Metric Sets and Tools
- Current Workgroup Activities
- Available Case Studies
- Educational Resources
- Benchmarking and Database
- MCC White Papers and Published Articles

To further support the implementation and effective use of performance metrics, a new, groundbreaking program called the MCC Ambassador Network has been launched. The network is comprised of experienced industry consultants who are familiar with MCC products and services relevant to their areas of expertise. MCC Members benefit from the insights these subject matter experts bring to MCC’s online forums. Additionally, you can search the

www.metricschampion.org
MCC Ambassador Network database to find consultants available to assist your organization with a variety of consulting engagements.

As a MCC member, your employees have access to metric sets and tools as well as the ability to participate in MCC member-only surveys and workgroups. Additionally, members receive substantial discounts on educational course registration fees and publications. Some educational webinars and case study presentations are offered exclusively to MCC members.

Once your organization has established a membership, a member of the MCC staff will schedule an onboarding session for you and your colleagues. This 30-minute online meeting affords you the opportunity to learn more about MCC products, and to ask questions that directly relate to your business.

To maximize the benefit of membership, we encourage you and your colleagues to establish individual user accounts so you can participate in online workgroup discussions and access training materials, metric sets and publications. Please see the MCC Member Welcome Guide for an overview of the MCC Member Web Portal and instructions for establishing user accounts.

For more information about membership benefits and pricing, visit MCC Membership area of the website or contact MCC Membership Coordinator, Terry Holland [tholland@metricschampion.org].

IV. Stay Informed
There are many different ways to stay up-to-date with MCC.

- The MCC public website is updated frequently to provide the industry with the latest MCC news in the following areas:
  - News and Member Activities: Upcoming news and events.
  - MCC News page: MCC news in chronological order.
  - MCC Events page: Upcoming events MCC staff will be attending.
  - MCC Metric Work Groups: Descriptions of MCC Metric Work Group activities available to MCC members.

- Join the Metrics Champion Consortium LinkedIn Group to learn more about MCC and stay abreast of new developments.

- Establish a MCC individual user account (please see How to Apply for an Individual User Account) to gain access to the MCC Member Portal. By doing so, you will add your email address to the member news distribution list.
V. How to Apply for an Individual User Account

*Please note that your organization must be a MCC member in order for your individual user to be activated by MCC.*

2. Click on the Setup User Account button located in the upper right corner.

3. Open the online form - please confirm that you are completing the Individual User Registration form (A).

I. Complete and submit the form. Please note that you will be asked to create a login name and password – keep this information because you will be asked to log into the account to complete the next part of the application (A). Additionally, you will have the option of signing up for workgroups (B). A description of MCC work groups is available at [MCC Metric Work Groups](http://www.metricschampion.org). Once you have signed up for a work group, you will be added the work group email distribution list and have access to the work group-specific webpage. If you are not ready to sign-up for a work group, you can sign-up at a later time (please see [Sign Up For Workgroups & Update Your User Profile](http://www.metricschampion.org)).
II. Once you have completed Step 4, you will receive a confirmation email with the subject “Thank you for Starting Your Application for MCC Membership!” Please ignore the instructions within this email. You are not required to do anything further.

III. MCC will notify you once your account has been activated. *It can take up to 2 business days to verify and approve your account. During this time you will not be able to access the MCC member only pages.* You will receive an email with the subject “Your MCC Membership Registration Notice” once your account has been activated. After you receive your registration notice you will be able to log onto the MCC Member Portal and have access to the MCC member-only web pages.

VI. **How to Access the MCC Member-only Web Pages**

a. After you receive your registration notice you will be able to log onto the MCC Member Portal and have access to the MCC member-only web pages. You may access the MCC Member Portal by visiting [www.metricschampion.org](http://www.metricschampion.org) and clicking on the orange **Member Login** button at the top of the page. For more information about MCC user account access, please see the MCC member portal.
b. Log onto the MCC Member-Only portal by using the Login Name and Password you set up when you created a User Account. If you have any issues with your MCC account, please contact MCC Customer Service.

c. Select the CLICK HERE to access our Member Only Website.
d. **MCC Member-Only Homepage:**

**Member News & Information**

- **Member News & Information**: Current news for all MCC members including such topics as upcoming and recent meetings, new surveys and the launch of new MCC initiatives.

**Member Action Items**

- **MCC Guide Review of Metric Sets**: The MCC is conducting a “checkup” review of its Clinical Trial Performance Metrics and 2014 Quality Metric sets. CLICK HERE to access the survey links and more information about the review. CLICK HERE to download the companion document “Overview of the MCC Metric Sets Guided Review Initiative”.

- **Open Surveys**: The MCC currently has several open surveys available for members to complete. CLICK HERE to view our list of open surveys and access the survey links.

**Member Action Items**: MCC posts action items such as metric feedback, survey links and work group sign-up requests in this section.

**Upcoming Meetings & Events**

- **Upcoming MCC Meetings**: CLICK HERE to find a listing of all upcoming MCC workgroup meetings and informational sessions. Please be aware that some of these meetings will require pre-registration.

- **Conference Dates & Discounts**: CLICK HERE to find a listing of all upcoming industry conferences where MCC executives will be in attendance and presenting. As a MCC member you will also have access to use discount codes for many of the industry conferences.

**Upcoming Meetings & Events**: Listing of all upcoming MCC workgroup meetings and informational sessions as well as upcoming industry conferences where MCC executives will be in attendance and presenting. As a MCC member you will have access to use discount codes for many of the industry conferences.
MCC Initiative Updates

White Papers  CLICK HERE to access our complete white paper list

Case Studies  CLICK HERE to access our complete case studies list

Meeting Publications  CLICK HERE to access a list of recent MCC meeting presentation slides and recordings.

SME Webinars  CLICK HERE to access our Subject Matter Expert Webinars

MCC Initiative Updates: MCC white papers, case studies, meeting presentations and archive recordings.

Website Index

Meetings & Workgroups

Access the MCC work group landing page that has a description of MC work group expectations and inks to all active, retired and future work groups.

Existing Metric Sets & Scoring Tools

Access to MCC metric sets and scoring tools ready for adoption. Members will be notified when new content is available on the page.
Access the MCC Subject Matter Expert Webinar archived recording library (free to MCC Members) and member discount codes to purchase training courses available at the MCC online store.

Access to the MCC Newsletters and articles library

Links to update user contact information, add/remove work groups, complete or renew organization-level membership

Access the MCC online store and member coupon codes to apply to store purchases.
VII. Sign Up For Workgroups & Update Your User Profile
1. Log onto the MCC Member Portal (see VI steps 1-3).
2. Select My Membership

3. After you click on My Membership, please select Update My Profile or Sign Up For Workgroups.
4. Complete updates and select submit to save changes.

VIII. How to Access Workgroup Webpages
1. Log onto the MCC Member Portal (see VI steps 1-3).
2. Select Meetings & Workgroups

3. After you click on Meetings & Workgroups it will take you to the MCC workgroup landing page that has a description of MC workgroup (WG) expectations and links to all active, retired and future WGs. Select the WG homepage you would like to visit. Please note that if you are unable to open a WG page, you need to add the WG to your user profile (see VII Sign Up For Workgroups & Update Your User Profile for details).
4. Each MCC WG webpage contains information about upcoming meetings, WG assignments, WG deliverables and more. The WG Resource Center has links to past meeting material, presentations and regulatory reference guides. An overview of WG goals and deliverables and important WG News are posted at the bottom of the webpage.

**Trial Master File Performance Metrics Working Group**

<table>
<thead>
<tr>
<th>MEETINGS</th>
<th>ASSIGNMENTS</th>
<th>RESOURCES</th>
<th>CONTACTS</th>
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</thead>
<tbody>
<tr>
<td>Next Meeting: 5 April 2016 10 AM EST</td>
<td>Guided Review of TMF Key Performance Questions CLICK HERE to download the companion document</td>
<td>If you would like to view Past Meeting Materials please visit the WG Resource Center</td>
<td>Linda Sullivan 317-622-0266 ext 102 <a href="mailto:l.sullivan@metricschampion.org">l.sullivan@metricschampion.org</a> (contact for WG questions)</td>
</tr>
<tr>
<td></td>
<td>MCC TMF Artifacts Mapping Tool short video</td>
<td>If you would like to view Regulatory Guidance Documents or Selected Articles please visit the MCC Resource Library</td>
<td><a href="mailto:customerservice@metricschampion.org">customerservice@metricschampion.org</a> (contact for website questions)</td>
</tr>
<tr>
<td></td>
<td>MCC TMF Artifacts Mapping Tool Survey</td>
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<tr>
<td></td>
<td>WORKGROUP DELIVERABLES</td>
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<td>Agenda</td>
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**Workgroup Overview**

**Working group is exploring:**

- How well the TMF process is being executed and managed throughout a study's start-
- How well the TMF process is being performed across studies.
- Criteria that defines an “acceptable level” of performance

**IX. How to Contact Us**

<table>
<thead>
<tr>
<th>Main Phone</th>
<th>1-317-622-0266</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membership Coordination</td>
<td><a href="mailto:tholland@metricschampion.org">tholland@metricschampion.org</a></td>
</tr>
<tr>
<td>Billing &amp; Payments</td>
<td><a href="mailto:billing@metricschampion.org">billing@metricschampion.org</a></td>
</tr>
<tr>
<td>Customer Service</td>
<td><a href="mailto:customerservice@metricschampion.org">customerservice@metricschampion.org</a></td>
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www.metricschampion.org