

# MTN Publications: MTN-020 General Information

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Pittsburgh, PA

2015 Regional MTN meeting: **ASPIRE team meeting** 

### **MTN Publications: Goals**

The MTN encourages and facilitates the publication of research conducted by the network or involving use of network resources

- Publications must meet consistent high standards
  - All MTN scientific publications need to undergo a multi-level review process to ensure this goal

## **Review Process: Groups**

- Publication planning, development and review of all MTN publications is supported by two MTN groups:
  - Protocol Publication Committee (PPC)
    - Specific for each MTN protocol
    - Includes Protocol Chair, Protocol Statistician, DAIDS Medical Officer, FHI Clinical Research Manager (CRM), other members
  - MTN Manuscript Review Committee (MRC)
    - Oversees publications from all MTN protocols
    - Includes MRC chair, Statistical and Data Management Center PI, Executive Committee Chair, Laboratory Center representative, BRWG and BSWG representatives, and MTN LOC Manuscript Coordinator

## **PPC Responsibilities**

#### Plan Publication Concepts

 Review and approve manuscript/abstract concepts suggested by protocol team members

#### Develop/Prepare/Prioritize

- Publication venue (meeting/journal)
- Timeline (data analysis; writing)
- Writing team: lead author and coauthors

#### Review/Approve and Ensure

- Accurate reporting (study design, conduct, analysis, conclusions)
- Format and style- journal/meeting requirements;
  general medical writing practices

## **MRC** Responsibilities

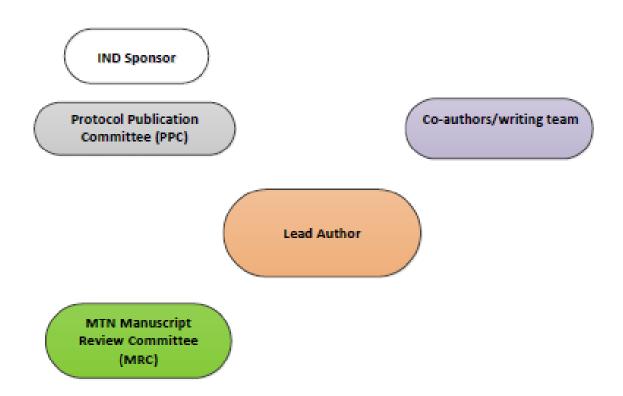
#### Review/Approve

- A blind- peer-review conducted by an MTN investigator with expertise in publication's topic
  - Accurate reporting (study design, conduct, analysis, conclusions)
  - General Medical writing quality (clear, concise)
- MRC coordinator selects the MTN reviewer and ensures
  - Participants confidentiality is protected
  - Acknowledgement of MTN and NIH support

#### **MRC Reviewers and Timelines**

- MRC reviewer pool:
  - Typically MTN members
    - Biomedical Science Working Group (BSWG) members
    - Behavioral Research Working Group (BRWG) members
    - Others
- Target MRC review timelines
  - Abstract submission to MRC:
    - 2 weeks prior meeting submission deadline
  - Review duration
    - Abstracts: 2-4 business days
    - Posters/oral presentations: 3-4 business days
    - Manuscripts: 10 business days

## Overview: MTN publications Development and Review Groups



# Overview of MTN Publications: Development and Review Steps

Review of publication concept by PPC Concept is added to publication plan and timeline via email (CRM) Publication is developed by lead author and reviewed by co-authors Review of publication by PPC and IND Sponsor Submission of publication to MTN MRC Review via MTN web-portal (MRC coordinator) **Review of publication by MTN MRC** 

Submission of publication by lead author to journal or conference

## **Lead Author Responsibilities**

- Submit a publication concept to PPC
- If concept is approved work with SCHARP statistician and co-authors to develop 1st draft of publication
- Submit for review/approval:
  - Co-authors
  - PPC
  - Sponsor
  - MRC
- Address reviewers comment at each review step
- Submit publication to venue
- Provide status updates and most up to date versions of the publication to Katie Schwartz.

### **General Guidelines**

- Publication order
  - Primary papers (based on analysis of primary study objectives/endpoints) must be published first, prior to secondary analyses
    - Exceptions are made on a case by case basis and must be approved by PPC and MRC

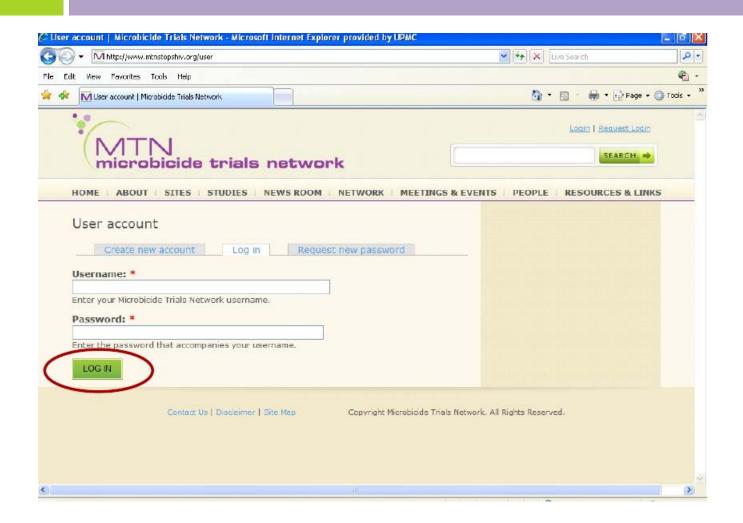
### **General Guidelines**

- All MTN manuscripts need to include an acknowledgment statement of MTN and NIH's support
  - see Resource section on MTN website
- All published MTN manuscripts need to fulfil the NIH Public Access Policy
  - After manucsript is accepted for publication the lead author needs to ensure that either the journal and/or lead author deposit the manuscript into the NIHMS system

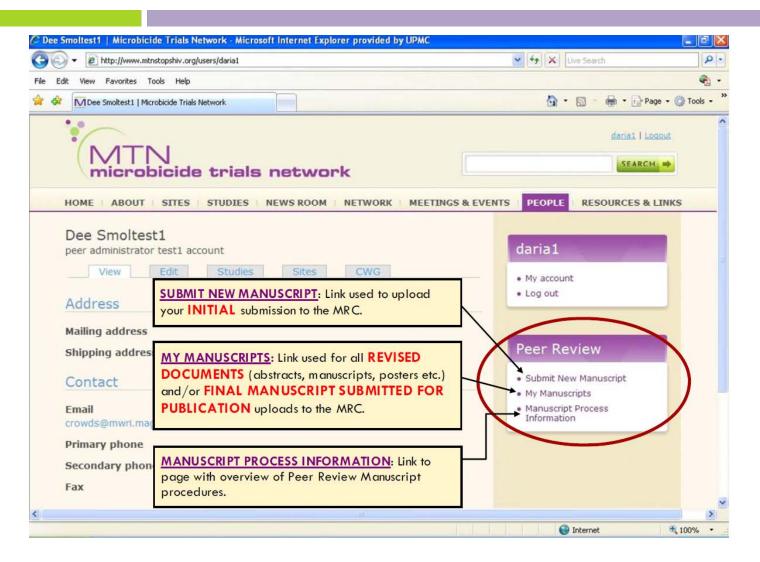
# How to submit publications to MRC review?

Use of Current MRC web-based module

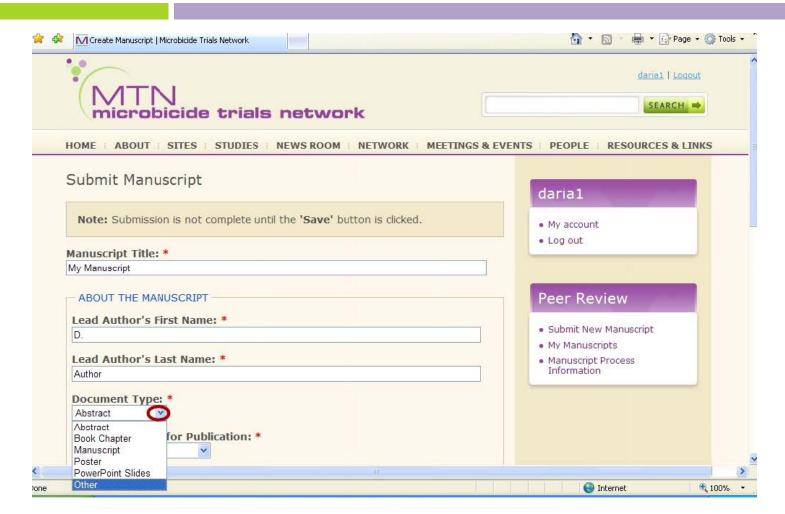
## **Lead Author- Login**



## **Current MRC submission process: Lead Author - Initial Submission**



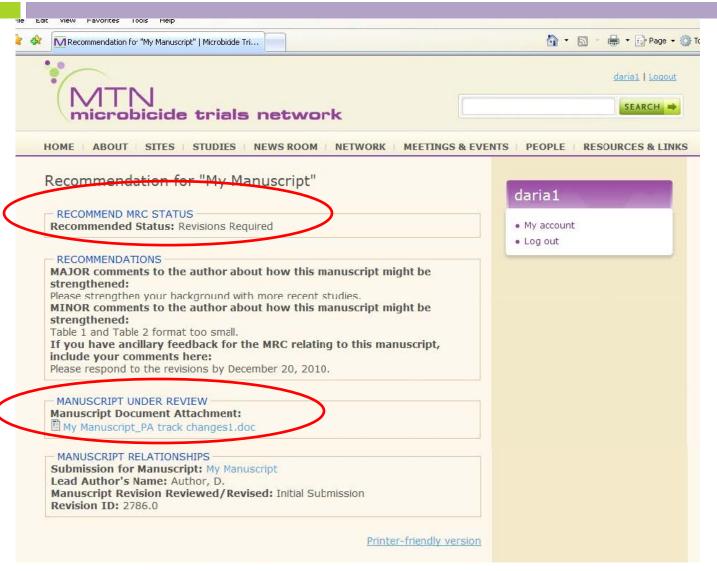
### **Lead Author-Initial Submission**



Use drop menu to select publication type and venue

Submission confirmation is sent to Author via an automated Email notification

# MRC Review Process: Reviewer's Comments



# Coming soon: New Web-based Publication Review System

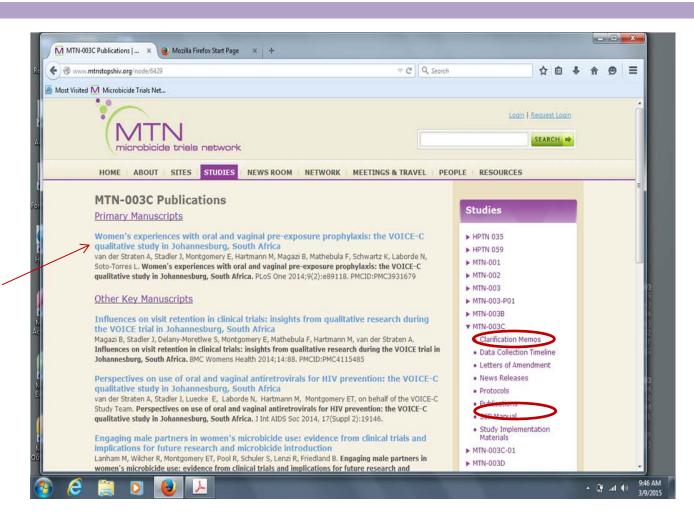
- A new publication management software was recently acquired by MTN
- The new software will support reviews of MRC + additional groups (PPC, Sponsor and possibly co-authors) via a web-based module.
- The new system is anticipated to be implemented for all MTN publications and across all MTN protocol teams in early 2016.

#### **MRC Review: Resources**

- Supporting tools are available on MTN website (See the Resources Tab, see the "Most Popular" column)
  - Detailed technical guidelines for use of:
    - MRC process: <u>Manuscript Review Process</u> (<u>MTN Peer</u> Review Module
    - MRC module : <u>How to use the peer review Module</u>
    - Soon: New publication module (to be provided after launch of new module network-wide use)

### **MTN Publications: Resources**

List of key
 manuscripts for
 each MTN
 study is posted
 on MTN
 website (link to
 PubMed
 abstract)



#### **MTN Publications: Resources**

- General MTN publication guidelines and policies
  - Publication Policy (MOP section 6)
- MTN poster and oral presentations templates
   (soon to be posted: specific templates to provided
   for key meetings)
- Acknowledgment statement
- Coming Soon: MTN publications (manuscripts) master list
- Coming Soon: Links to NIHMS submission resources

 For any general questions about MTN publications and publication policy – please contact Orly Aridor aridoro2@mwri.magee.edu

### extra

## Overview of MTN Publication Development and Review Procedures

Review of concept for publication by PPC Concept is added to publication timeline

- Author completes Study Concept Sheet and submits to PPC (FHI 360 CRM)
- PPC approves, rejects or requests revisions

Manuscript/abstract is developed by lead author/co-authors

- If **PPC** approves, a writing team is created as needed and the concept is included in the Protocol Publication Timeline, which is shared with MTN MRC
- Author and writing team develop the manuscript/abstract

Review of manuscript/abstract by PPC and IND Sponsor

- Author submits manuscript/abstract to PPC via FHI 360 CRM
- PPC reviews and provides feedback to author
- Once PPC approves, FHI 360 CRM or Protocol Chair sends to **IND Sponsor** for review (per the terms of the study CTA)

Submission of manuscript/abstract to MTN MRC Review

 Once PPC and IND Sponsor comments have been addressed and Protocol Chair has provided final approval to submit for MTN MRC review, author uploads to the MTN MRC Peer Review module via the MTN web page

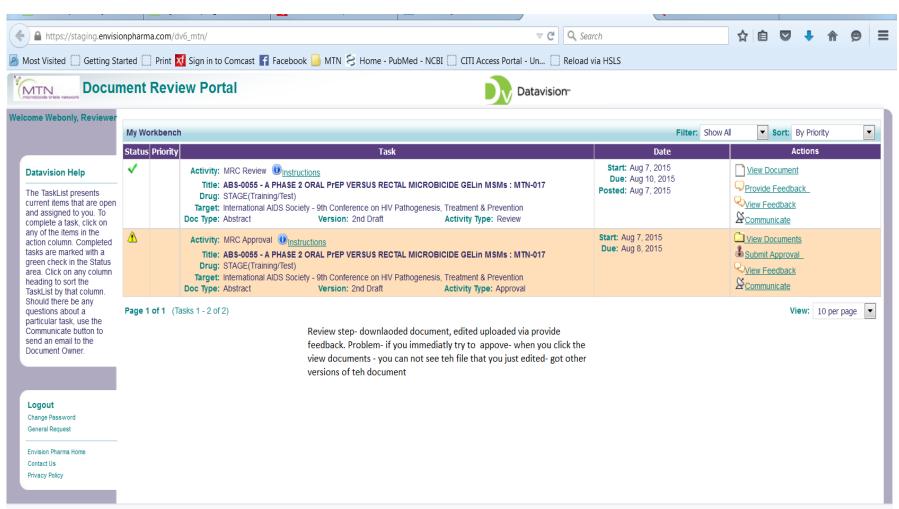
Review of manuscript/abstract by MTN MRC

- MRC designates a MRC Reviewer (blinded review)
- MRC Reviewer provides (via the module) a recommendation (Approved, Not Approved, Or Revisions Required) + major and minor comments
- If revisions are required author revises and resubmits

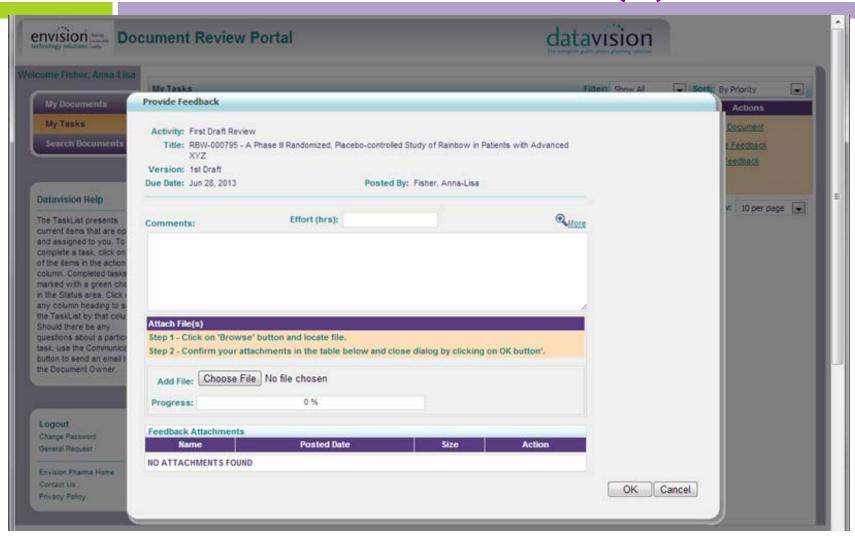
Submission of manuscript/abstract by lead author to journal or conference

• Once manuscript/abstract is approved by MRC, author may submit to journal or conference

# Document Review and Approval Secure Web Portal (1)



# Document Review and Approval Secure Web Portal (2)



### **MRC Review: Overall 2**

- MRC Reviewer provides (via the MRC module):
  - Decision:
    - Approved
    - Not Approved
    - Revisions required
  - Specific recommendations:
    - Details provided in comment section (major and minor comment boxes) and may include specific comments/revisions provided within the document (see attachment)

## **Application Automated Emails**

- Review type (co-author, PPC, IND Sponsor, MRC)
- Indicate task (Review, Approve)
- Provide link to publication document
- Indicate task deadline
- Reminders (sent one day prior to due date)

#### Dear Manuscript Review Committee (MRC) reviewer

This is a request to **review** the following Manuscript entitled "A Phase II study of Oral PreP vs Rectal microbicide gel in MSMs: MTN-017" by the following authors: XXXXXXXXXX, available to you through the web link below: https://staging.envisionpharma.com/dv6\_mtn.

Please review and provide feedback by Sep 4, 2015.

## MTN Publications: Review Process Goals

#### • Ensure

- Publications reflect accurate and clear reporting of MTN study design, conduct and analysis
- Publications are developed in a collaborative fashion
- Participants confidentiality is protected
- Comply with NIH policies
  - NIH Public Access Policy
  - Acknowledge MTN and NIH support