**DMID answers to OCICB Questions:**

* **How will DMID be using this repository?**
  + All TMF documentation will be finalized at the CRO and final documents for each protocol will be sent to DMID staff to store in the electronic repository
    - **How are the final documents to be sent to DMID?**
      * The CRO has offered to send the final documents via physical export on CD, DVD, or Flash drive with metadata and exported audit trail, OR through a secure File Transfer Platform (sFTP) with metadata and audit trail. Our preference is the sFTP method at this time, but will re-evaluate if necessary.
    - **Will the CRO be importing the documents directly into the repository or will DMID be managing the import?**
      * If the sFTP is used, this would be a system to system transfer, however, DMID will create a QC checklist to ensure that all data has been transferred properly.
    - **Will TMF documents only be uploaded through the import function? Or will there be manual document uploads as well?**
      * Since this initial phase of the project entails developing just the repository for uploadeding final eTMFs developed by the CRO, we will only need to upload through the import function. However, we do understand there may be documents that trickle in after the eTMF is final and we need to have a contingency plan; but we do not want to hold up this project for that purpose. In the future when we move towards developing in-house TMFs for DMID studies, there will definitely be a need to upload manually.
* **Will there be any branch or team-specific folders needed for storing protocols?**
  + At this time, we will only be transferring final eTMFs into the repository and we will not need additional folders.
* **Will all protocols be stored in the general repository with no additional organization needed?**
  + Yes, all protocols will be stored in the general repository.
* **Are any additional requirements for Division specific folder structure outside of the hierarchical DIA model?**
  + No, there are no additional requirements needed at this time.
* **Who are the primary users that will need access to the eTMF Repository?**
  + The primary users will be determined by the role of Editor and Read Only.
* **Are there edit or read-only permissions that must be associated with each folder?**
  + Yes and those permissions will be determined by the roles created for the users.
* **Who or which roles will be responsible for creating a new protocol folder?**
  + The Editor role, once determined, will be responsible for creating a new protocol file.
* **Of these metadata fields, what needs to be tagged with the documentation that is imported from the CRO?**
  + Audria will compare the metadata used in the Veeva Vault system to see which ones stand out as required fields and will get back to the team on this.
* **Do the values remain the same?**
  + To be determined
* **Are there any manually entered or required fields?**
  + Not at this time.
* **How will search functions be performed in DMID?**
  + For the most part, we will use search for inspection purposes and for our own internal purposes.
* **What search and filter capabilities are required?**
  + We’d like the possibility of searching across protocol and across sites, but this is not an immediate need and we don’t want to hold up the project to build this out.
  + **Which metadata attributes will be used to search/filter**
    - Metadata attributes include the site, site number, site PI and a search for specific types of documents such as notes to file/filenotes, agreements, relevant communications…just to name a few.
* **Will searches only be performed at the individual protocol level?**
  + As stated above, we’d like to be able to search across protocols, but this is not an immediate need.
* **Are any exporting features needed for the data?**
  + Yes, we will need exporting features to export reports that have been generated and to download documents, etc.