

# R Submission Pilot 3 Meeting Minutes

Pilot 3 Team

2023-03-24

Pilot 3 team should be able to see updated meeting minutes here on a weekly basis.

## 24Mar2023 - Minutes by Joel Laxamana

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- Submission Pilot3 - ADaM Check In
- Meeting Organizer: Thomas Neitman, Joel Laxamana
- Participants: Joel Laxamana, Thomas Neitman, Kangjie Zhang, Ben Straub, Robert Devine, Declan Hodges, Nicole Jones, Dadong Zhang, Lei Zhao
- Summary: Discussed tasks still in progress
- Project Board: <https://github.com/orgs/RConsortium/projects/7>
- Meeting Recorded: Yes : [https://drive.google.com/file/d/1Gt7l2NOorQe43jVJ-McCaBKE\\_-vW\\_j4X/view?usp=sharing](https://drive.google.com/file/d/1Gt7l2NOorQe43jVJ-McCaBKE_-vW_j4X/view?usp=sharing)

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### 1. Declan.

- Updating renv.lock with most current snapshot. updating packages including admiral .10.
  - Datasets need updates with new snapshot
  - Joel to merge 77 to main and Declan to create new issues for ADSL, ADADAS, ADTTE
  - ADLBC and ADAE are good to go.

### 2. Nicole

- Reviewing ADLBC specs and populating AVAL with correct derivation.
- Reviewing codelist

### 3. Dadong

- Reviewing ADLBC specs with Nicole.
- Issue with max values - fix derivation issue for when subject's values are all missing NA.
  - Will update specs on this. See #82.

### 4. Ben

- Will work on updating the ADRG

### 5. Kaz

- Summarize discrepancies on attribute and format issues for all datasets
- Metacore issue on removing duplicate formats. all details in #87
- These are minor issues, so long as we document in wiki we should be good.

### 6. Robert

- Issue 83 adtte specs look good.
- Declan to add Robert to adtte issues per #77.

7. Lei

- Will work on updating the ADRG

8. Thomas/Joel

- Update R Consortium Submissions WG on Pilot 3 : [https://docs.google.com/presentation/d/1-aZEW8HAUm\\_T3ywXWKGNIxQP7Ez0DHgN2BaRNQZJ3k/edit?usp=sharing](https://docs.google.com/presentation/d/1-aZEW8HAUm_T3ywXWKGNIxQP7Ez0DHgN2BaRNQZJ3k/edit?usp=sharing)

@channel Pilot 3 ADRG to update : [https://drive.google.com/drive/folders/15Ec2FCjuiCothwdilUOlFGgPKEG78BFF?usp=share\\_link](https://drive.google.com/drive/folders/15Ec2FCjuiCothwdilUOlFGgPKEG78BFF?usp=share_link) Please let me know if you all have access to these or not. Thanks.

## 17Mar2023 - Minutes by Joel Laxamana

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- Submission Pilot3 - ADaM Check In
- Meeting Organizer: Thomas Neitman, Joel Laxamana
- Participants: Joel Laxamana, Thomas Neitman, Kangjie Zhang, Ben Straub, Robert Devine, Declan Hodges
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1.

- {admiral} v0.10 (or maybe even update CRAN snapshot and update all packages we are using.)

**ACTION : Decision to update admiral - adadas locf derivation now available. We need to update renv.lock then do renv::restore().**

**Is everyone ok with updating CRAN snapshot and all packages? See <https://github.com/RConsortium/submissions-pilot3-adam/issues/77#issuecomment-1476000593> and input your comments/responses.**

2.

- Pinnacle 21 report

**ACTION : Check on ADTTE & ADLBC derivation specs : Bingjun and Nicole**

- All other dataset specs OK, per Declan (ADSL), Kaz (ADADAS), ADAE (Phani/Joel)

**ACTION : I've created git issues for all datasets, please close issue in git to formally track that the specs are ok now.**

- This is the most up-to-date specs, where the define has 0 issues in Pinnacle 21 now. [https://docs.google.com/spreadsheets/d/13T15AS69ENeHktMofEQD4QBOg\\_moY-mU/edit?usp=sharing&ouid=103991081896680964420&rtoref=true&sd=true](https://docs.google.com/spreadsheets/d/13T15AS69ENeHktMofEQD4QBOg_moY-mU/edit?usp=sharing&ouid=103991081896680964420&rtoref=true&sd=true)
  - Please use your gmail account to open this link. Direct message me in slack your gmail so that I can share the doc.

3.

- Joel to continue to resolve ADADAS.AVAL length, will reach out to Kaz if needed.
  - working on branch 10 to update this before PR.

**Update : length now fixed and P21 issue now resolved.**

4.

- ADRG needs to be worked on. How best to collaborate
  - Decision - we will continue with google docs. Since this is an open source pilot study, there is nothing too confidential to worry about. Feel free to create temporary google accounts if you don't have one, then share your gmail with me so that I can share google docs with you. [Thanks Ben and Declan for sharing your accounts with me. I've added you to the google doc list where you should be able to now access the meeting recordings (or at least request access) and the google docs.]

**ACTION : To update ADRG, we can**

1) copy text from Pilot 1 to Pilot 3 adrg. Pilot 1 adrg : <https://github.com/RConsortium/submissions-pilot1-to-fda/blob/main/m5/datasets/rconsortiumpilot1/analysis/adam/datasets/adrg.pdf>,

2) Take Pilot 3 proposal : [https://github.com/RConsortium/submissions-pilot3-adam/blob/main/vignettes/fda/R\\_Submission\\_Pilot\\_3\\_ADaM\\_FDA\\_Execution\\_Proposal\\_02Dec2022.pdf](https://github.com/RConsortium/submissions-pilot3-adam/blob/main/vignettes/fda/R_Submission_Pilot_3_ADaM_FDA_Execution_Proposal_02Dec2022.pdf) and include this info into the Pilot 3 ADRG (should list out all steps for FDA to unpack the Pilot 3 project.)

3) This is the current base ADRG directly coming from P21 : [https://docs.google.com/document/d/13xMUVQgZMmXd1igdZNUQy1Pc-WxoMxL7/edit?usp=share\\_link&ouid=103991081896680964420&rtpof=true&sd=true](https://docs.google.com/document/d/13xMUVQgZMmXd1igdZNUQy1Pc-WxoMxL7/edit?usp=share_link&ouid=103991081896680964420&rtpof=true&sd=true) We then just need to mash all of this information into one cohesive Reviewer's guide that is specific to Pilot 3.

One recommendation would be to just copy Pilot 1's ADRG and update it with the Pilot 3 proposal/project unpacking steps and information.

5.

- Once above is up to date, we need to move over programs to esub repo, then Robert Devine can unpack and test.

**Announcements :**

- Thomas leaving Roche to pursue new position. Congrats to Thomas! You will be missed at Roche, but glad to know you'll still be Co-Leading/Collaborating with us in this open source Pilot 3 project.

**10Mar2023 - Minutes by Joel Laxamana**

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- Submission Pilot3 - ADaM Check In
- Meeting Organizer: Thomas Neitman, Joel Laxamana
- Participants: Joel Laxamana, Kangjie Zhang, Ben Straub, Robert Devine, Dadong Zhang, Declan Hodges, Nicole Jones, Lei Zhao, Bingjun Wang
- Summary: Discussed tasks still in progress
- Project Board: <https://github.com/orgs/RConsortium/projects/7>
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- Joel has made updates to specs to help resolve our P21 issues. Only looking at the define alone, there are currently 300+ issues, which should be resolvable as we remove all reference to datasets, codelists, variables from datasets that we are not generating in Pilot 3.

Define: R-Consortium > R-tetsing > A...

+ Import Export Preview Copy

Properties Datasets Variables Value Level Codelists Terms Methods Comments Analysis Displays Analysis Results Issues P21 Versions

Search

RuleId	Variables	Values	Message	Description
DD0080	Method	ADLBHR2A1LO	Method <method> is not referenced	Only Methods that are referenced from a Variable or Value Level metadata should be included in Define.xml. Define-XML specification represents Methods as MethodDef elements within MetaDataVersion element.
DD0080	Method	ADLBHR2A1LO	Method <method> is not referenced	Only Methods that are referenced from a Variable or Value Level metadata should be included in Define.xml. Define-XML specification represents Methods as MethodDef elements within MetaDataVersion element.

**ACTION to Lei Zhao :** Thanks to the discussion within the team, we should be able to resolve the issues directly in P21. Then Lei will : <https://github.com/RConsortium/submissions-pilot3-adam/issues/61>

1)Update define directly in P21 to resolve issues with the specs.

2)Generate define.xml to validate against the ADaM .xpts

3)re-export the updated Excel sheet so team can rerun their ADaM scripts against the new specs to make sure metatools and xportr functions are calling in the specs appropriately.

- Robert working on KM plot to PR today.

**ACTION to Robert :** call on {Pilot3} package for utility functions, path to the ADaMs generated in our Pilot, output filename with -pilot3 extension.

- Bingun updated demog table and is in PR already.

**ACTION to Joel :** Review PRs and merge accordingly.

- Steven updated script for addt.R to call on {Pilot3} and path to the ADaMs generated in our Pilot.

We are almost there!

## 02Mar2023 - Minutes by Joel Laxamana

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- Submission Pilot3 - ADaM Check In
- Meeting Organizer: Thomas Neitman, Joel Laxamana
- Participants: Joel Laxamana, Kangjie Zhang, Ben Straub, Robert Devine, Phani Tata, Steven Hae-sendonckx
- Summary: Discussed tasks still in progress and went through slides here : [https://docs.google.com/presentation/d/1-aZEZw8HAUm\\_T3ywXWKGNIXQP7Ez0DHgN2BaRNQZJ3k/edit?usp=sharing](https://docs.google.com/presentation/d/1-aZEZw8HAUm_T3ywXWKGNIXQP7Ez0DHgN2BaRNQZJ3k/edit?usp=sharing)
- Project Board: <https://github.com/orgs/RConsortium/projects/7>
- Meeting Recorded: Yes <https://drive.google.com/file/d/1LfZoTR08p7DtY71UUkr6S43LDQEPIUkf/view?usp=sharing>

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- Joel has made updates to labels in specs to help resolve our P21 issues. Upon individual runs of each datasets and checking the attributes specific to the P21 issues, these should now be resolved.
  - all data now in main and ready for refresh of P21 run
  - explanation for VISNUMEN should be added to P21
  - issue with ADSL.RACEN, will share updated specs on RACEN codelist which should resolve this issue

- Joel sent Declan the updated specs through slack as .xlsx.
- Joel demoed quick run in `main` using current `renv` and all works ok.

**ACTION : To Steven, hopefully a pull of `main` and `renv_restore()` should resolve. Keep us posted.**

- e-Submission packaging
  - Cleaning up & finalizing ADaM R scripts
  - Sourcing Pilot 3 data into the TLF programs
  - Make sure timestamps are in place
  - Then bring scripts over to Pilot3 FDA repo : <https://github.com/RConsortium/submissions-pilot3-adam-to-fda>

**ACTION : ADRG - Lei/Joel to generate from P21**

- Joel will try to run P21. Lei to pack up .xpt and define.

**ACTION : Updating specs, for those who worked on the datasets to be responsible for updating specs. Will create issues.**

- Create a batch run pipeline to run our ADaMs in order then the TLFs. See `targets{}` package - Ben/Thomas

**ACTION : Ben Straub - Remove extra comments in `adtte.R`**

To note : `admiral{}` 1.0 release Mar 6 - rerun all programs and check for issues.

## 24Feb2023 - Minutes by Joel Laxamana

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- Submission Pilot3 - ADaM Check In
- Meeting Organizer: Thomas Neitman, Joel Laxamana
- Participants: Joel Laxamana, Kangjie Zhang, Nicole Jones, Ben Straub, Robert Devine, Phani Tata, Declan Hodges, Bingjun Wang
- Summary: Discussed tasks still in progress and went over P21 issues.
- Project Board: <https://github.com/orgs/RConsortium/projects/7>
- Meeting Recorded: Yes [https://drive.google.com/file/d/1jh9z9ivfBph7v-yBEiTMvBuglbEm\\_uI9/view?usp=sharing](https://drive.google.com/file/d/1jh9z9ivfBph7v-yBEiTMvBuglbEm_uI9/view?usp=sharing)

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- ADLBC now in `main`.

**ACTION : Nicole to add discrepancies in QC Findings with 3 date variables date vs numeric.**

- ADTTE first draft to main ready for merge - Thanks Bingjun, Robert and Ben

**ACTION : Bingjun - add data format differences in QC findings**

**ACTION : Robert - KM plot should run soon after `adtte` is in `main`**

**ACTION : To all assigned tables or plot, please update all TLF programs to use capital `.R` extension instead of lowercase `.r`**

**ACTION : include timestamps in TLF outputs.**

Thomas/Ben/Joel - Run ADaMs and TLFs in correct order so that timestamps make sense, especially due to data dependencies. Suggest ADSL, ADAE, ADADAS, ADLBC, ADTTE

**ACTION : For all assigned to working on datasets, please update specs with new TDF define found. See issue #10 and look out for new issues for these actions for each dataset spec.**

- Vignettes to be added down the road post-submission
- Next meeting go through a process flow of data, TLFs in a project area going into eSUB.
- P21 issues shared by Lei and now listed for all to review and resolve in issue #61

**ACTION : All please confirm the P21 issues are now resolved in #61.**

## **17Feb2023 - Minutes by Joel Laxamana**

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- Submission Pilot3 - ADaM Check In
- Meeting Organizer: Thomas Neitman, Joel Laxamana
- Participants: Thomas Neitman, Joel Laxamana, Kangjie Zhang, Nicole Jones, Ben Straub, Robert Devine, Phani Tata, Declan Hodges
- Summary: The meeting was conducted with each participant providing an update about their project activities and overall discussion about next steps to submission process
- Project Board: <https://github.com/orgs/RConsortium/projects/7>
- Resolution: Continue Development (Backlog:8, In Progress:6, In Review: 3, Done: 12)
- Meeting Recorded: Yes

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Joel - Started meeting.

Ben Straub - Pilot 3 website now up and running. Need updates to authors in DESCRIPTION file to those in Pilot 3. Follow Pilot 1 and do Vignettes for datasets, in Pilot 3, still on the table and could be valuable to public viewers of the Pilot 3 repo for convenient viewing of our work. Can help advocate R use.

Kanjie - Summarized the common issue amongst datasets. Further noted the newer specs found in the TDF repo that should be used to bring over derivations to the Pilot 3 specs/define.

**ACTION : @all to review Issue #57.**

Declan - updated TLF, issue #31 now in draft PR once ADLBC is merged.

Nicole - ADLBC EOT obs are now in! YES!!! Now matching with original dataset.

**ACTION : Nicole will update PR with new ADBLC updates. THANKS for sticking with it, Nicole!**

Robert - working on PR #21 [ADTTE]. Close to matching with original. Thanks to Bingjun and Steven developing ADTTE. Labels are now added. XPT seems to not be up-to-date.

**ACTION : Need ADTTE script to switch to xportr{} instead of haven{} when generating .xpt.**

Phani - ADAE now in main. Great work, setting up the foundation. Will take new work to help with tables.

**ACTION : Assigned to Demog table program, reading Pilot 3 ADSL. <https://github.com/RConsortium/submissions-pilot3-adam/issues/29#issuecomment-1436393205>**

Joel - Found more up-to-date specs, where correct derivations should be brought over to the Pilot 3 specs. Created an ADAE vignette.

**ACTION :** @all please review new specs in Issue #10 to make sure we capture the correct derivations and bring them over to our current Pilot 3 specs. Need to bring these specs into the main/adam branch.

**ACTION :** Lei to begin submission process and check P21 issues with our current Pilot 3 specs.

**ACTION :** We need to begin setting up the adam-to-fda repo with our Pilot 3 info : <https://github.com/RConsortium/submissions-pilot3-adam/issues/53#issuecomment-1435035929>  
Due end of Feb.

Thomas Neitman - Closed meeting.

Meeting Recording : [https://drive.google.com/file/d/1aV7NoGPE\\_k58ufTGUq8NYwDOdyqGPAep/view?usp=sharing](https://drive.google.com/file/d/1aV7NoGPE_k58ufTGUq8NYwDOdyqGPAep/view?usp=sharing)

## 10Feb2023 - Minutes by Robert Devine

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- Submission Pilot3 - ADaM Check In
- Meeting Organizer: Joel Laxamana
- Participants: Joel Laxamana, Kangjie Zhang, Ben Straub, Steven Haesendonckx, Benjamin Wang, Robert Devine
- Summary: The meeting was conducted with each participant providing an update about their project activities.
- Project Board: <https://github.com/orgs/RConsortium/projects/7>
- Resolution: Continue Development (Backlog:14, In Progress:4, In Review: 3, Done: 6)
- Meeting Recorded: Yes

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- Joel Laxamana - Greetings and Meeting Setup.
- Robert Devine - Discussion of recent progress around Issue #5 (ADTTE) and requested to advance the issue from 'In Progress' to 'In Review'. Next Check In follow up with Issue Assignees. Noted participation in the CDISC {admiral} Hackathon (In Progress) with work on ADTTE and other ADaM datasets. Work concurrently on Issue #32.
- Ben Straub - Discussion of focus around PR (Pull Request) => main in reference to the Pilot3 repository
  - Issue #59: Create vignettes for Datasets like Pilot1 did for Tables
  - Issue #58: List out team in Description File
  - Issue #57: Common Issues facing Datasets
  - Issue #55: Establish Rotating Minute Takers Going forward
- Kangjie Zhang - Discussion of the define updates, common issue across datasets, the CDISC {admiral} Hackathon, code quality team awareness, alignment of specs to {admiral} Hackathon. {Thomas Neitmann} has posted the updated spec file in the {admiral} Hackathon Slack channel which was linked during the Check In to Pilot3. The updated spec was posted February 8, 2023 in Slack #admiral\_hackathon.
- Joel Laxamana - Discussion of recent progress around ADAE dataset which is now 'In Review'. Requested {Steve Haesendonckx} to review the ADAE dataset which was linked in GitHub by {Ben Straub}.
- Steve Haesendonckx - Discussion of the alternative submission proposal and the R Consortium / R Infrastructure
  - requests to continue alignment with previous R Submission Pilots. The Pilot3 Team indicated interest to possibly revisit the proposal as a Pilot[3.5] at a later date. Noted possible data format

differences in ADTTE across the pilots. Accepted request to review the ADAE dataset. Worked with {Nicole Jones} on ADLBC dataset that is 'In Review'.

- Benjamin Wang - Discussion about Issue#5 ADTTE contribution and PR with a request for Comment and Review.
  - Initiated availability to further contribute with additional task assignments. Responded to {Ben Straub} that Issue #29 (Table - Demographics and Baseline Characteristics) would be of interest for assignment in the Project3 GitHub.
- Joel Laxamana - Farewell and Meeting Adjourns

Meeting Recording : <https://drive.google.com/file/d/1YyQOTIpoLNA0IJCQ34-9aTEA9Pn62X-Q/view>

## 03Feb2023 - Minutes by Joel Laxamana

R Consortium meeting conflict with Pilot 3 catch-up today

1. Joel & Phani
  - ADAE in PR.

**ACTION : message from Thomas to review this : <https://pharmaverse.slack.com/archives/C04968ES7T4/p1675170902021159> need to check. Also need to implement solution for TRTEMFL discrepancy solution #38**

- since we are matching with the original ADAE, if we update this we need to see if it creates discrepancies and need to document in our QC findings.
2. Kanjie
    - Populated Value level metadata tab has been updated for ADAS
    - Need to focus on quality of define
  3. Nicole
    - Reviewed Thomas's comments on ADLBC and addressed them.
    - still have 30+ discrepant records particular to end of treatment. Endpoint variables are missing for those 30 values. In progress at this time.
    - qa\_adlbc.R created and all match except for those 30 records.
    - attribute discrepancies will need to check hours vs date. see how it impacts table program. if no impact we can document differences in QC findings wiki.
  4. Declan
    - No updates
  5. Dadong
    - Will move on to tables/graph tasks.
  6. AOB
    - Where to find table and graph programs.

**ACTION for those that can work on updating the output programs, they can be found here :**

<<https://github.com/RConsortium/submissions-pilot3-adam/tree/main/vignettes>> Each of the .RMD scripts t

Meeting Recording : <https://drive.google.com/file/d/1D2sUlnpLaGV8BGb2GeS5tJePinOMRaEd/view>



## 27Jan2023 - Minutes by Joel Laxamana

1. Joel
  - ADAE now has PR to main.
  - diffdf() still showed a few messages with format.sas discrepancies.
  - Next step to look into the Time to First Dermatologic Event table.
  - Per Phani, Treatment-Emergent Flag has to be updated using #38 solution from Kaz
2. Ben S.
  - no updates today
  - working on admiral-Hackathon
  - Phani asks if working on this Pilot3
3. Steven
  - will follow up with Nicole on ADLBC
4. Kanjie
  - need to add value-level metadata to define for ADAS and ADTTE, manually.
  - 2 issues created
  - we're updating define in google sheet then will download to excel to create a new define.xml
  - Ben S. mentions metacore functions that could help generate define for us.
5. Kanjie demonstration on
  - using metacore package to read in specs as an metacore object.
  - we need to update define in order to best update the metadata when applied to the variables in our datasets.
6. Steven discussion on alternate eSUB package approach and discussion.
  - Post meeting notes - Joel brought this up to the R Consortium core group and they've strongly suggested we follow the same submission steps as Pilot 1 and 2 for consistency and knowing that FDA have already accepted the packages for these prior Pilots.
  - This can be brought up again after Pilot 3 has been submitted.

Meeting Recording : [https://drive.google.com/file/d/1\\_qA3ct8YtTLvtronKCsviVBiRuD7LmEcx/view](https://drive.google.com/file/d/1_qA3ct8YtTLvtronKCsviVBiRuD7LmEcx/view)

## 20Jan2023 - Minutes by Joel Laxamana

1. Joel
  - ADAE reviewing FLP script, also added back ADSL variables. Look into missing ADAE variables, but seems the select() function in the script was just missing the variables we needed.
  - DATASET.JSON not ready for this Pilot 3 FDA submission yet, but still looking at using .xpt for this pilot.
  - Still reviewing comments and updates to proposal.
2. Phani
  - ADAE variables are available that Joel mentioned.
  - Looking into ADAE labels to finalize.
  - After ADAE will pick up new issues.
  - parquet files proposed to FDA for option submission? Webinar : <https://www.youtube.com/watch?v=nqJsLSLd39A&t=5s> see 14:28
3. Kanjie
  - LOCF function in admiral being updated. Need to add one more parameter in ADADS.

- ADSL codelist solution suggested by Kaz. Sample code will be written in another branch and will request ADSL authors to review and merge to their dev branch if approved by them.
4. Steven
- Worked with Nicole on ADLBC updates.
  - Raised awareness on .txt submission package. Will set a time at next meeting to discuss proposal.
5. Ben S.
- Project board set-up : <https://github.com/orgs/RConsortium/projects/7>

**ACTION : ALL REVIEW meeting recording below to see Ben's demo on project board (10:22)**

- ADLBC in PR, but still has issues.
- ADAE still in progress.
- For new issues, please add them to the backlog (11:55). This will help to see if issues need to be re-assigned.
- Package down site, still in progress.

**ACTION : Ben work with Steven to help set-up github pages.**

6. Declan

- Thomas created new area to document discrepancies between datasets we generated and original datasets.

**ACTION : All add any new corrections needed from original datasets**

<<https://github.com/RConsortium/submissions-pilot3-adam/wiki/QC-Findings>>

7. AOB

- last 2 datasets ADLBC and ADTTE
- ADAS and ADSL already main
- ADAE now reading in the Pilot 3 generated ADSL
- Once all datasets are in main, then we need to complete the Table/Graph scripts.
- Then complete eSUB package.

Meeting recording : [https://drive.google.com/file/d/1ZuGjY4vZBuBg3\\_-qKwnCAeLhBhXuKy\\_Y/view](https://drive.google.com/file/d/1ZuGjY4vZBuBg3_-qKwnCAeLhBhXuKy_Y/view)

## **13Jan2023 - Minutes by Joel Laxamana**

1. Declan

- ADSL QC, SAS and R differences. Issue seems to be with original ADSL not Pilot 3 ADSL. What is approach to fix?
  - Thomas suggests differences like this we need to document to note the updates we had to make to follow the documented define.
  - Joel mentions that there is this tab which we can use to document differences and update the specs with the corrected approach. [https://docs.google.com/spreadsheets/d/1gLm\\_IITesD8jUoygJ3rRQmLj1Wmt5P4NrteDogTWaI4/edit#gid=1009681230&range=F1](https://docs.google.com/spreadsheets/d/1gLm_IITesD8jUoygJ3rRQmLj1Wmt5P4NrteDogTWaI4/edit#gid=1009681230&range=F1)
  - LB.VISIT incorrectly set as derivation not in ADLBC.

**ACTION to Declan - Create a separate document to note differences.**

**ACTION to Joel : remove datasets in define that we will not be submitting in Pilot 3.**

**ACTION to Steven : double check if there were issues in codelists.**

**ACTION to Nicole : also found issues in specs in ADLBC, work with Stephen to update ADLBC specs appropriately.**

2. Ben

- Packagedown update, needs admin access
- Project board/Kanban generation

3. Nicole

- ADLBC compare to original dataset. Looks good, but missing  $\geq 50$  records vs original dataset.

**ACTION : Steven, Nicole and Dadong to review spec derivations to see if these are where discrepancies are.**

4. Steven

- Reviewing Pilot 3 proposal to the FDA and proposed an alternate approach to submission. Issue #37. <https://github.com/RConsortium/submissions-pilot3-adam/issues/37#issuecomment-1347960472>

**ACTION : Steven to share proposal in a separate meeting or we prolong our standup to an hour to continue further discussion on this.**

5. Kanjie

- Rerun primary table as used with ADADAS, made updates to table script only due to updated R version and package versions, nothing else. Upon generation, due to discrepancies found in ADADAS with the original dataset, the results show minor differences.

**ACTION :Kaz to document these differences in a doc. Same doc where ADSL differences are captured.**

- ADSL codelist can use metatool functions rather than writing separate code for formatting per specs. Kaz created an issue #45
- ADAE TRTEMFL discrepancy solution #38

**ACTION : Phani and Joel to update ADAE FLP with Kaz's suggestions.**

**ACTION : PR ADAE and ADLBC to main as draft so that others can see the scripts for these.**

6. Bingjun

- ADTTE specs seem to be missing in define.
  - Updating specs to include ADTTE specs

7. Yutong

- Catching up with the team.

**ACTION : looking through new issues to assign herself.**

8. AOB

- CDISC working group proposing on using DATASETS.JSON for FDA submission instead of .XPT

**ACTION : bring this question to R Consortium group meeting.**

Meeting adjourned.

Meeting recording : <https://drive.google.com/file/d/1OH12R8zkuGEz39AQ4DkhNUq9DIZmG3WD/view>

## **06Jan2023 - Minutes by Joel Laxamana**

Happy New Year and Welcome back!

1. Joel L.
  - FLP ADAE majority completed by Phani (Great work, Phani!).
  - Going through Pilot 3 proposal review, new comments have come in which are being addressed.
    - Question from Ben - how will the R package work when submitted to the FDA via eCTD?
    - Answer - The package will essentially be an R package of the project, including all of the R package utility functions we used in pilot 3 (as listed in the renv.lock file) and all of the project work scripts that generate the ADaMs and Tables/Graph. Alternatively, instead of a package a simple .txt file for all of the packages used and another .txt file for all ADaM and Tables/Graph script can simply be delivered as well with instruction for either approach written appropriately in the ADRG. Goal of this pilot is for FDA to be able to receive R submissions in Clinical Trial work that is understandable to unpack, readable and/or executable.
2. Ben S.
  - Github actions
    - check everyone's codes in that the code runs on Windows, Mac, Linux
    - PR done and needs to get merged. Joel to merge.
    - Package down - new issue #42 to update all Pilot 1 info to Pilot 3. Create website.
3. Declan
  - ADSL updated and merged to main, but need to double check if been compared to original ADSL. He'll follow-up.
4. Lei
  - Check that we're using the correct define. Issue #10.
    - needs github access
    - work on ADRG
5. Kanjie
  - ADADS merged to main, but when compared to original ADADS discrepancies came up.
    - Admiral recent released `derive_locf_records()`, limited to only AVAL variable as last observed record carried over, but does not include other variables needed. Kaz made updates to function herself to fix issue on her end. Working with admiral to update in next release. At this time has saved function in function folder in pilot 3 repo. See #50
    - Second issue noted in #39 with original ADADS.
6. Phani
  - updating labels in ADAE. Derivation of all variables are complete.
  - issue with TRTEMFL derivation issue #38
  - will work with Joel to get scripts pushed to git
7. AOB
  - Need to follow up on ADLBC.
  - Tables working group meetings vs submission working group meetings
  - Review that our work in Pilot 3 is creating ADaMs originally used in Pilot 1 to generate Tables/Graphs, then take the Pilot 1 Table/Graph scripts and source our ADaMs to generate the Tables/Graphs.

Meeting adjourned.

Meeting Recording : <https://drive.google.com/file/d/1b4MG98ljC4Yf4CFzpT40qEeSi6nQKbLL/view>

### 23Dec2022 - Minutes by Joel Laxamana

Meeting cancelled, because it's time to take a break and hang out with our Families and Friends. Have a well-deserved and relaxing break everyone. We'll pick it up again next year! ~Thomas and Joel



### 19Dec2022 - Minutes by Joel Laxamana

1. Ben S. - brought up package down sites for Pilot 3. Easy to do from Posit.

**ACTION** to Ben S. - work on Pilot 3 package down site. Update to show our progress on Pilot 3 ADaM. <https://pkgdown.r-lib.org/>

<https://github.com/RConsortium/submissions-pilot3-adam/issues/11>

2. Kanjie - ADAS almost done. Working on one more parameter discrepancy. Working using new functionality in `admiral` 0.9.0 per updated `renv.lock`.

**ACTION to Kanjie - work on table :** <https://github.com/RConsortium/submissions-pilot3-adam/issues/30> compare against Pilot 1.

googlespreadsheet define working well so far. Updating the descriptions correctly so that the `metacore{}` package can import well. Able to import excel directly. At some point we'll need to update the Value Level metadata.

3. Joel - still working on ADAE. Phani has worked on half of ADAE and still needs to derive 13 more variables. I took time to meet with Phani set up his Posit Cloud and github connection, so he was able to push his script up to git, where then I can pull his work to continue updates. Delivered Pilot 3 proposal to R Consortium for review : <https://github.com/RConsortium/submissions-pilot3-adam/issues/37>
4. Some notes for everyone on Pilot 3. As we are all trying to work in the same environment on Posit or on your local computer, before making any pushes or PRs, please make sure you're not changing any of our environment files (e.g. `renv.lock`) in your branch, then pushing up and accidentally merging to main (though we do have the main branch protected, we're only human and something could get through). As users pull from main and merge to their dev branches to get the updates, any change in the environment when doing a restore could show errors in their program due to different package versions. Pay attention to detail and mindful of the changes being made in your PRs. Thanks everyone for your cooperation!

**SEE YOU ALL NEXT YEAR.**

**ACTION to Joel - Create deadlines on main Read.me file so that everyone has transparency on work that needs to be done at a certain time. Maybe create a Kanban board on the issues.**

## 09Dec2022 - Minutes by Joel Laxamana

1. Joel
  - getting updated define.xml and converting to google spreadsheet, editable by everyone. Notes on the versioning, since Pilot 3 is based off of Pilot 1 it makes sense to use the define from Pilot 1 to continue using in Pilot 3. The CDISCPILLOT define seems to have had a lot of issues in P21, but the Pilot 1 define only had 8 issues per P21 v5.2.
    - a. Current define spreadsheet here for team members to edit as needed : <https://github.com/RConsortium/submissions-pilot3-adam/issues/10#issuecomment-1342005671>
  - New issues created for Tables and Graphs. Please assign yourself to work on these and test the Pilot 3 ADAMs as source data in these output programs to see if they match the Pilot 1 outputs.
2. Kanjie
  - `metacore{}` issue, not able to read in define.xml if there is a metadata label empty in the specs, but the `metacore{}` author/developers have worked on a fix for this to allow empty labels. With this update, there could be a new version of `metacore{}`.
  - Continuing updates to ADAS specs in the new spreadsheet as needed.

**ACTION to Kanjie :** update `renv.lock` in main branch to the `metacore{}` version we need to have aforementioned update. Then all Pilot 3 users can run these steps <https://pharmavers.e.slack.com/archives/C04968ES7T4/p1671196678615089> to update their branches, including `renv::restore()` to get the updated metacore package.

3. Dadong
  - working on ADLB with Nicole. Current environment is on his working computer, but will plan to transition to Posit Cloud so that he will be using the same environment as the rest of the team.

**ACTION to Thomas : Current Posit Cloud is now using R 4.2.2, where there is a check in startup that notes we should be using 4.2.1. But this should not be the case. Thomas will create an issue to remove the R version check so that we all just use the most current version in Posit Cloud. Current issue :**

R version change [4.2.1 -> 4.2.2] detected when restoring session; search path not restored  
Connected to your session in progress, last started 2022-Dec-23 20:09:44 UTC (14 minutes ago)

4. Thomas

- Final comments on ADSL pull request. Declan will be taking on these updates and will be the first program and dataset to be merged to main branch.
- ADAS may soon be merged before the holiday by Kanjie.

5. Ben S.

- released a new version of Admiral 0.9.0 and should update `renv.lock` file.
- Thomas mentioned we already proposed a CRAN snapshot from the 1st of November, but with the update needed for both `metacore{}` and `admiral{}`, we need to be clear in our final documents what CRAN snapshot we will be using.

**ACTION/Request to Ben S. : Can we get `renv.lock` updated to also read in new Admiral version?**

6. Declan

- working on ADSL PR. Working with Steven and Thomas, ADSL should be in merged to main soon.

7. Robert

- working on ADTTE. Has derived ADTTE with the ADAE dependency from the CDISCPilot/Pilot 1 ADaM datasets, not purely deriving from SDTM. May have a draft of this ADTTE in a week or so. Once ADAE is ready in Pilot 3, then ADTTE should source the Pilot 3 ADAE in the final run.
- Note about testing. Working in 'Windows' vs 'Posit Cloud'. Once FDA receives Pilot 3 package, they may be running in Windows and not using Posit Cloud, like us.
- Confirms that he uses `.R` suffix vs `.r`
- has also removed the `ad_` prefix in program filename as readable code would normally not have this prefix.
- Found a Merck document that describes the updates to the define. Could be helpful for traceability.

**ACTION/Request to Robert : Can you share the Merck document describing the updates to the define and post it here : <https://github.com/RConsortium/submissions-pilot3-adam/issues/10> ? Maybe even get the `define.xml` for to push to our Pilot 3 repo.**

**ACTION/Request to Ben S. : At the end of our pilot 3, we need to test that our package runs fine on a regular Windows environment, not Posit. As most likely our stakeholders will just be running on their local computers.**

8. Phani

- Progress on ADAE, date variables updated, still working on 13 more variables. Still working on his local machine and will need help with setting up Posit and Git.

9. Lei

- Will help with issue #10.

10. Bingjun (Ben)

- Working on ADTTE, using `admiral{}`, not `dplyr{}`.

11. AOB :

- FOLLOW-UP question from Steven H. : The derivation of all highlighted variables can not be `ADLB.XXX = LB.VISITNUM`, especially not variables that are taken from demographics like `AGE`.
  - Joel Response : It seems the erroneously documented derivations for these variables are not the datasets we are working with in Pilot 3. For now, we can ignore these if they do not impact the datasets we are working on. I tried to create an issue in the TDF repo, but ‘issues’ weren’t accessible to me. Feel free to add an issue if you have access : <https://github.com/phuse-org/TestDataFactory>



P21

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ID	Name	Type	Description
ADLBCPV.VISITNUM	Algorithm to derive ADLBCPV.VISITNUM	Computation	LB.VISITNUM
ADLBC.VISITNUM	Algorithm to derive ADLBC.VISITNUM	Computation	LB.VISITNUM
ADLBH.A1LO	Algorithm to derive ADLBH.A1LO	Computation	LB.VISITNUM
ADLBH.ABLFL	Algorithm to derive ADLBH.ABLFL	Computation	LB.VISITNUM
ADLBH.ANL01FL	Algorithm to derive ADLBH.ANL01FL	Computation	LB.VISITNUM
ADLBH.ANRIND	Algorithm to derive ADLBH.ANRIND	Computation	LB.VISITNUM
ADLBH.AVAL	Algorithm to derive ADLBH.AVAL	Computation	LB.VISITNUM
ADLBH.BASE	Algorithm to derive ADLBH.BASE	Computation	LB.VISITNUM
ADLBH.BNRIND	Algorithm to derive ADLBH.BNRIND	Computation	LB.VISITNUM
ADLBH.CHG	Algorithm to derive ADLBH.CHG	Computation	LB.VISITNUM
ADLBHPV.A1HI	Algorithm to derive ADLBHPV.A1HI	Computation	LB.VISITNUM
ADLBHPV.A1LO	Algorithm to derive ADLBHPV.A1LO	Computation	LB.VISITNUM
ADLBHPV.ABLFL	Algorithm to derive ADLBHPV.ABLFL	Computation	LB.VISITNUM
ADLBHPV.ADT	Algorithm to derive ADLBHPV.ADT	Computation	LB.VISITNUM
ADLBHPV.ADY	Algorithm to derive ADLBHPV.ADY	Computation	LB.VISITNUM
ADLBHPV.AENTMTFL	Algorithm to derive ADLBHPV.AENTMTFL	Computation	LB.VISITNUM
ADLBHPV.AGE	Algorithm to derive ADLBHPV.AGE	Computation	LB.VISITNUM
ADLBHPV.AGEGR1	Algorithm to derive ADLBHPV.AGEGR1	Computation	LB.VISITNUM
ADLBHPV.AGEGR1N	Algorithm to derive ADLBHPV.AGEGR1N	Computation	LB.VISITNUM
ADLBHPV.ALBTRVAL	Algorithm to derive ADLBHPV.ALBTRVAL	Computation	LB.VISITNUM
ADLBHPV.ANL01FL	Algorithm to derive ADLBHPV.ANL01FL	Computation	LB.VISITNUM
ADLBHPV.ANRIND	Algorithm to derive ADLBHPV.ANRIND	Computation	LB.VISITNUM
ADLBHPV.AVAL	Algorithm to derive ADLBHPV.AVAL	Computation	LB.VISITNUM

Found 160 records (filtered from a total of 510)

**HAPPY HOLIDAYS TO ALL TAKING EARLY BREAK FOR THE EOY! WILL SEE YOU NEXT YEAR.**

## **02Dec2022 - Minutes by Joel Laxamana**

Just as a quick update to today's catch-up meeting (apologies, I forgot to record this meeting as well).

1. Our current focus (the meat of the project) is just to continue working on ADaM programming. The organization and final areas where all of our documents, programs, directory packages will go can be decided at a later time. To help set priorities, my suggestion would be :
  - a. Posit Cloud and github setup. Make sure we're all working in the same environment.
  - b. First line programming of ADaMs (e.g. define updates, checks against the CDISC pilot ADaMs using {diffdf} )
  - c. Once we {diffdf} checks pass, then run these source datasets into Pilot 1 programs.
    - i. Please study and reference this doc : <https://github.com/RConsortium/submissions-pilot1-to-fda/blob/main/m1/us/report-tlf.pdf>
    - ii. Since we forked the Pilot 1 repo, we should be able to get Pilot 1 programs from here : <https://github.com/RConsortium/submissions-pilot3-adam/tree/main/vignettes>
    - iii. Update Pilot 1 programs to make sure they work in our current environment (e.g. R v4.2.1, any package updates needed due to different R version we are using), per <https://github.com/RConsortium/submissions-pilot3-adam/issues/6>
2. Will need to work with @Phani Tata github set-up off-line to save versions of his development. Thanks, Phani for continuing with the ADAE program development.
3. We need define updates per @Kangjie Zhang request. A proposal has been made here if anyone can help with this : <https://github.com/RConsortium/submissions-pilot3-adam/issues/10#issuecomment-1335565702>
4. @Bingjun Wang working on ADRG. You may use content in this proposal for ADRG. See : <https://github.com/RConsortium/submissions-pilot3-adam/issues/28#issuecomment-1335528257>
5. @Nicole Jones has updated Pilot 3 main repo info. Thank you! Now continuing on with ADLBC with @Dadong Zhang .
6. ADSL updates are underway as I see communication here : <https://github.com/RConsortium/submissions-pilot3-adam/pull/27>
7. ADTTE also upon finalization : <https://github.com/RConsortium/submissions-pilot3-adam/pull/21> .

For all working on the datasets, recall the approach is to use the the Pharmaverse packages, i.e., {admiral} package.

Announcement : Proposal for Pilot 3 FDA execution will be delivered to the rest of the R Consortium team soon. If you'd like to take a read updated proposal is here, for now, and will soon be in the RConsortium submissionswg repo .

Let @Thomas Neitmann or I know if you have any further questions.

## **28Nov2022 - Minutes by Joel Laxamana**

Unfortunately we didn't record last week's stand up. But given the holidays in the US it was a very short meeting anyways with only 4 attendees. I think the most important decision we made was to write all ADaM scripts as plain .R files and not .Rmd files. Please use admiral/pharmaverse function if available and only rely on dplyr/tidyverse as a fallback option. Also, please open a pull request as soon as you have a draft program available. That way the progress on your programs is transparent for all team members. Just follow what @Kangjie Zhang did.

## **14Nov2022 - Minutes by Joel Laxamana**

Thanks, @channel for those able to join today's Pilot 3 weekly catch-up meeting. Just to bullet :

1. Welcome @Declan Hodges to the team! Great to have more participation in this pilot. Currently,

Declan is working to get his environment set-up on his end to begin work. Any current issues open in the repo, please feel free to assign yourself, Declan.

2. Overall, it seems all others have been able to set up an instance of the working environment on R Studio Cloud just fine and all ADaMs seem to be in good progress.
3. An issue came up regarding the define.xml , which doesn't seem to correspond very well with the define.pdf for. We've scoured the CDISC Pilot repo to see if there were any newer updates of the .xml file, but have not found one. Action to @Lei Zhao :
  - a. We could reach out to someone from the CDISC pilot team (maybe add an issue in their repo) to find out if we can get an updated define.xml.
  - b. Alternatively, if there is an .xls out there matching the define.pdf , we could use that .xls to read into to P21, then re-export a define.xml that way. -@Dadong Zhang @Kangjie Zhang, please feel free to chime in further on this topic to elaborate on the issues that you are seeing. -R : <https://github.com/RConsortium/submissions-pilot3-adam/issues/10>
4. Discussion about workflow. For those new to github, it may help to have a small video tutorial on how to collaborate through git. Two approaches discussed :
  - a. For each dataset a branch has been created. If there are 2+ contributors to a branch, they can continue working in the same branch, but just requires clear communication on when updates are pushed and when other contributors can pull to get those updates to continue working further until completion until final script is ready to merge back to main.
  - b. For each dataset a branch has been created. Additionally, for each contributor, they should also make their own branch for their own development/updates to the script, then PR to dataset branch to get the updates, resolve conflicts, and merge to completion, until final script is ready to merge back to main.

## 02Nov2022 : R Submission Pilot 3 - ADaM Kick-off - Minutes by Joel Laxamana

- Team Roster: <https://docs.google.com/spreadsheets/d/1BW9Jojo4bAgxbfM96nXooh2QAlU6CKwk19pInxmI2VA/edit?usp=sharing>
- GitHub repo: <https://github.com/RConsortium/submissions-pilot3-adam>
- We added SDTM from CDISC Pilot Project to the Pilot 3 repo so that our R ADaM programs can source these domains.
- We also added ADaMs from the CDISC Pilot Project for ADaM developers can {diffd} on.
- {admiral} set-up demos : <https://www.youtube.com/channel/UCxQFEv8HnqM01DXzdQLCy6Q/videos> [https://pharmaverse.slack.com/files/U028SDSVAR0/F0461A8E4CC/hello\\_\\_\\_admiral\\_\\_\\_\\_\\_2022-10-07\\_14\\_04\\_gmt\\_2\\_.mp4](https://pharmaverse.slack.com/files/U028SDSVAR0/F0461A8E4CC/hello___admiral_____2022-10-07_14_04_gmt_2_.mp4)
- Work environment is here : [https://login.rstudio.cloud/invite?code=nwG-pLCv8EP2fR7j2p9ZuEJ17P0mOBgmqhOyANhL&space\\_name=R+Submission+Pilot+3+-+ADaM](https://login.rstudio.cloud/invite?code=nwG-pLCv8EP2fR7j2p9ZuEJ17P0mOBgmqhOyANhL&space_name=R+Submission+Pilot+3+-+ADaM)
- If you already created a branch for a dataset to work on then you can get current updates by running the following commands in the RStudio terminal:

```
git checkout main
git pull
git checkout <your_branch>
git merge --no-edit main
```

- SAP : <https://pharmaverse.slack.com/files/U028SDSVAR0/F04A5FFSGA3/cdiscpilot01.pdf>
- Define : <https://github.com/RConsortium/submissions-pilot3-adam/issues/19>