

# Fall 2020 SWOG PHARMACEUTICAL SCIENCES CMTE & DRUG INFORMATION SUBCMTE Meeting – Virtual

## SUMMARY

**Date:** Wednesday, September 23, 2020

**Time:** 10 am – 12 pm CT

### Agenda:

#### Committee Reports:

1. [Committee Administrative reports](#) – Siu Fun Wong
  - [Attendee introduction](#)
  - [Minutes/Meeting summary report approval](#)
  - [Introduction of new members](#): Jane Rogers, Michelle Yu, Aida Ulloa
  - [New Chair of DI subcommittee](#) – Aida Ulloa
  - [Summary report of Chair and committee activities](#)
    - [S2007 protocol review](#)
    - [Drug Interaction Standardized language in protocols](#)
    - [ORP Manual Chapter 6 update](#) (Matt Boron)
  - [Leadership transition plans](#)
2. [Drug Information Sub-Committee Report](#) – Aida Ulloa
  - [Approval of Drug Information Procedures and templates](#) – All
    - [Updates of PSC manual](#)
    - [Updates of SharePoint](#)
  - [Drug Information activities updates](#)
    - Drug Information Write-up requests – N = 9 (Ramucirumab, encorafenib, binimetinib, sacituzumab govitecan, ibrutinib, AMG510, avelumab, entecavir, tenofovir disoproxil)
  - [Feedback from Drug Information Residents/Program Directors](#) – Kim Redic & Janet Mighty/representatives
  - [Protocol Review activities](#) – Holly Chan/Jorge Avila
  - [Drug Interaction Initiative Updates](#) – Dan Hertz

3. [Study Drug Handling and Patient Education Handout follow up](#)
  - ORP committee interest - K Abueg
  - Submission to CIRB to minimize concerns of institutional IRBs - All
4. [BEACON standardized orderset updates](#) – Jane Rogers
5. [Digital Engagement Committee](#) – Dan Hertz
6. [Committee Webpage in SWOG Website](#) – Rivka Siden
7. [Pharmacist Liaison Reports](#) – All
  - Review of Pharmacist Liaison Assignment List
  - Disease Committee Liaison Pharmacist Reports

## **ADDITIONAL INFORMATION**

[Appendix A: SWOG Protocol Drug Interaction Standardized Language](#)

[Appendix B: Pharmaceutical Sciences Committee Web Page on SWOG Website](#)

[Appendix C: Pharmacist Liaison Assignments](#)

[Appendix D: Pharmaceutical Sciences Committee Membership List Fall 2020](#)

## Committee Administrative Reports

0:00:00

Committee Chair Siu Fun Wong opened the meeting with one introduction:

- Matthew Eng representing Stats Office



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## Attendee Introduction

0:00:25

Eng introduced himself.

- Represents SWOG Data Management Center in Seattle
- First group meeting ever
- Pharmacist by training

Wong asked Eng about his role at the Stats office being a pharmacist by training.

- Eng said he is a data coordinator
- Ensures submitted data is correct

Wong asked whether any first-time attendees wanted to introduce themselves.

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## Meeting summary report approval

0:02:05

Wong noted meeting summary had been sent to committee members for approval.

- Was recorded by people supporting the virtual meeting
  - Sent to members to review
  - Feedback received
  - No major changes requested
-

- Summary of meeting was approved

## Introduction of new members

0:02:44

Wong welcomed Jane Rogers, who had attended meeting previously and is now an official member of the Pharmaceutical Sciences Committee (PSC). Invited Rogers to introduce herself.

- Rogers thanked group for opportunity to join committee
- Pharmacist at MD Anderson for years
- Joined SWOG in 2018 on GI Committee
- Recently been welcomed to PSC
- Eager to get more involved

On invitation from Wong, Michelle Yu introduced herself:

- Second-year pharmacy resident at Johns Hopkins Hospital
- Residency is in investigational drug and clinical research
- Brand new to PCS and looking forward to helping out
- Completed one drug section for PCS and looks forward to many more

## New chair of DI Subcommittee

0:04:10

Wong asked Aida Ulloa to introduce herself, noting she was already taking a leadership role.

- Ulloa emphasized she was excited to be part of Drug Information (DI) Subcommittee and was ready to work with members to have positive impact on work of PSC
- Said she would do her best and invited members to offer suggestions, guidance, ideas, and feedback

Wong noted she had sent out announcement after last group meeting to introduce Ulloa as new chair of DI Subcommittee. Asked Ulloa to say a bit about herself.

## SWOG PHARMACEUTICAL SCIENCES COMMITTEE and DRUG INFORMATION SUB-COMMITTEE JOINT MEETING

### Agenda

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Location: Virtual Meeting  
Time keeper: TBD  
Minute Recorder: TBD

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    - o Drug Interaction Standardized language in protocols
    - o OPR Manual Chapter 6 update (Matt Boron)
  - Leadership transition plans
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    - Updates of ~~SWOG~~ ~~SWOG~~
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    - o Drug Information Write-up requests – N = 9 (Ramacirumab, encorafenib, binimetinib, sacituzumab, givinostat, ibrutinib, AMG510, avelumab, entecavir, tenofovir disoproxil)
  - Feedback from Drug Information Residents/Program Directors – Kim Redic & Janet Mighty/representatives
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  - ORP committee interest - K. Abzug
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4. BEACON standardized ~~updates~~ updates – Jane Rogers
5. Digital Engagement Committee – Dan Hertz
6. Committee Website in SWOG Website – Rivka Siden

- Ulloa said she was originally from Mexico
- Came to US in 1996
- Studied at Colorado State University for both bachelor's and master's
- Studied virus that causes leukemia called HTLV1
- Studied signal transduction that led virus to activate and replicate, and fell in love with signal transduction
- In doctoral work studied contractions in myometrium to prevent them and premature birth
- With this project she fell in love with microRNAs and that world, which hides so much knowledge
- After graduation, joined food company to study brassica plants and their genetics for about 6 years
- Fascinating time because brassica is a polyploid, so it was a complex system
- Goal was to make oils healthier
- Realized, though, that plants are not in core of her passions, so decided to move into new opportunities on other side of spectrum
- Joined oncology clinical research department at UC Health and has been there just over 4 years
- Has worn many hats there:
  - Helped manage contracts and financials
  - Worked with regulatory and data management pieces
  - Served as liaison between pharma and institution's PIs
  - Now focused on research coordination
- Research coordinator role has allowed her to learn about clinical trials and all involved with them to help patients navigate that journey
- Joining this committee has already allowed her to learn scientific knowledge from members and incorporate it into her work life
- Thanked group for welcoming her

Wong noted that next agenda item would reveal PSC has already been keeping Ulloa busy.

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## Summary report of chair and committee activities

0:09:20

Wong identified this agenda item as something that has been requested by members who wanted to know about other PSC activities beyond drug information requests and protocol review.

- Some of these items go just to Wong's desk and may not involve entire committee or may involve only select members based on their expertise
- Members wanted more well-rounded view of activities PSC undertakes

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### *S2007 protocol review*

0:10:10

Wong spent much time since last committee meeting reviewing S2007 protocol moving through rapid review process.

- This involves DI review (Section 3) and review of entire protocol at early stage of development
- This protocol includes complex information requiring great deal of input from pharmacy side, including many drug interactions

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### *Drug interaction standardized language in protocols*

0:10:58

Through this review and review of another protocol Wong recognized PSC needs to do more to standardize language in protocols on drug interactions

- Found tables often used to list interactions, but tables are often difficult to update
  - Wong has had discussion with Operations Office, primarily protocol coordinators, on agreement to standardize language of drug interactions in protocols
  - Also agreed to use more web links because they keep information current and reduce risk that of forgetting to update information in the protocol
-

- Drug interactions are complicated processes, but PSC needs to design this information to make it as simple and direct as possible, because most protocol users do not have strong pharmacology backgrounds
- Wong has drafted content and solicited input from Dan Hertz and Lauren MarCath
  - MarCath is not a PSA member but a fellow of Dan Hertz. She was instrumental in creating the drug interaction project with Hertz. The project is still ongoing under Hertz
- Project is developing platform that Wong hopes will be used in real time
- Now doing work to confirm utility and accuracy of platform
- Dan Hertz will explain more about this if he is able to join the call today

0:13:40

Wong displayed platform template in slide ([Appendix A](#)).

Wong said they created a document with generic language.

- Goal was a simple statement in Section 3
- Typically don't put detail information in there
- But Section 3 does need an alert about drug interactions
- This alert statement shown in slide:
  - Alerts reader about what drug interaction may be: enzyme, transporter, QT prolongation, etc.
  - Then sends them to Section 7 for details

Section 7 is treatment plan.

- At appropriate location, created several types of statements to address specific study drug divided into enzyme ...
  - substrate
  - inhibitor or
  - inducer
- Includes examples
- User will fill in blanks in brackets or select appropriate choice

### Section 3 Drug Information

#### Drug Interactions:

Concomitant administration of ["Study Drug"] with inhibitors/inducers of [e.g. CYP, UGT1A1, p-gp] may alter the pharmacokinetic or pharmacodynamics properties of the ["Study Drug"]. See Section 7.X for details.

### Section 7 Treatment Plan

*Please select the appropriate option(s) and select/fill in the information in the [ ] as appropriate, plus the respective reference listing(s):*

["Study Drug"] is a substrate of enzyme (e.g. CYP#X#, UGT1A1). Concurrent administration of the strong/moderate inhibitors or inducers of the enzyme [should be avoided during study participation]/ [warrant trial exclusion] to avoid increased or decreased systemic exposure of the ["Study Drug"].

["Study Drug"] is a strong/moderate inhibitor of enzyme (e.g. CYP#X#, UGT1A1). Concurrent administration of the enzyme substrates [should be avoided during study participation]/ [warrant trial exclusion] to avoid increased systemic exposure of the substrates.

["Study Drug"] is a strong/moderate inducer of enzyme (e.g. CYP#X#, UGT1A1). Concurrent administration of the enzyme substrates [should be avoided during study participation]/ [warrant trial exclusion] to avoid decreased systemic exposure of the substrates.

Lists of CYP3A4 inhibitors or inducers are accessible from:  
<https://drug-interactions.medicines.uu.edu/MainTable.aspx> OR consult local institutional pharmacists.

Lists of common UGT1A1 substrates are accessible from:  
<https://www.drugbank.ca/uncat/q?utf8=%E2%9C%93&searcher=drugs&query=UGT1A1+substrate> OR consult local institutional pharmacists.

Lists of common UGT1A1 inhibitors are accessible from:  
<https://www.drugbank.ca/categories/DBCAT002664> OR consult local institutional pharmacists.

- Can also select name of enzyme
- Talks of strong vs. moderate inhibitor vs. inducer of enzyme
  - PI or protocol coordinator will select
- Depending on level of interaction, wording can say avoid drug or exclude user from trial
- Foundational structure of statement is provided
- Provides links
  - This has been changed based on input from MarCath and Dan, who did lot of background research
- Wong noted that the CYP link applies to all CYPs not just CYP3A4; statement will be updated

0:18:24

Wong noted second page gets into tricky area: transporters.

- Transporter interactions are not as well studied, and available information is not as complete as it is for enzymes
- She did recently have a protocol that included a transporter
- Had been going back and forth on whether to include transporter statement, but some protocols do use them
  - However, keep in mind that clinical evidence re transporters is not as strong as for enzymes
  - Only site platform currently recommends is FDA site
  - FDA has area on clinical substrate inhibitors
    - No information on inducers
    - Hence template includes statements for only transporter substrates or inhibitors
- For every reference site, wording also recommends user consult local institutional pharmacist
  - Wong thinks this might help improve quality of output
- Last, template also includes statement on QT prolongation
  - Could be caused by drug or could increase risk of its being caused by concomitant drug

Lists of common UGT1A1 inducers are accessible from:  
<https://www.drugbank.ca/categories/DBCAT003925> OR consult local institutional pharmacists.

["Study Drug"] is a substrate of transporter [e.g. P-gp, BCRP, OATP1B1 or 3, OAT1 or 3, MATE1 or 2K, OCT2]. Concurrent administration of the inhibitors or inducers of the transporter [should be avoided during study participation]/ [warrant trial exclusion] to avoid increased or decreased systemic exposure of the ["Study Drug"].

["Study Drug"] is an inhibitor of transporter [e.g. P-gp, BCRP, OATP1B1 or 3, OAT1 or 3, MATE1 or 2K]. Concurrent administration of the transporter substrates [should be avoided during study participation]/ [warrant trial exclusion] to avoid increased systemic exposure of the substrates.

Examples of clinical substrates and inhibitors of transporters [e.g. P-gp, BCRP, OATP1B1 or 3, OAT1 or 3, MATE1 or 2K, OCT2] are accessible from:  
<https://www.fda.gov/drugs/drug-interactions-labeling/drug-development-and-drug-interactions-table-substrates-inhibitors-and-inducers> OR consult local institutional pharmacists.

["Study Drug"] can [cause QT interval prolongation and ventricular arrhythmia]/[increase QT prolongation risk of concomitant drugs]. Concurrent administration of these agents [should be avoided during study participation]/ [warrant trial exclusion].  
 Lists of drugs known to have QT prolongation risk are accessible from (requires free registration):  
<https://www.crediblemeds.org/> OR consult local institutional pharmacists.



- MarCath also provided useful website link here
  - Wong noted site requires free registration
  - Doesn't want people to be tied up by payment for subscription fees
- Wong also wanted to clarify that pharmacists usually have access to additional sites
  - Most require subscription
  - But not all SWOG sites have subscriptions
  - Hence, they selected the free sites for the proposal
  - They also recommend users contact their institutional pharmacist if they have one
  - Or users can contact PSC

Wong apologized for not sending this template out to PSC members before meeting; document was just completed.

- She noted several places needing fine tuning
- Will share with Quality Initiative Committee members to get their input
- Includes broad spectrum of SWOG leaders
- Wants to ensure this is appropriate for wide use

Questions?

Kristine Abueg was very impressed with this as a research coordinator coping with this issue daily.

- Found this extremely clear
- Will be of great use
- One suggestion while reviewing:
  - Emphasize that this section be cross-referenced with Section 5, the eligibility criteria
  - Because first thing to be done when enrolling patient is make sure their current med list won't be an issue

Wong noted this and said she would add to the source document.

Wong asked members to send her email with any additional feedback.

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- Will update some areas and send members updated version after this meeting
- Noted group works as a team and wants this to be a document that will help in complicated, challenging area of drug interaction

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## ORP Manual Chapter 6 Update

0:25:27

Wong referred to ORP review Chapter 6 update.

- As she has not been in practice in several years, she asked Matt Boron to do review of chapter
- Finished and returned to ORP

## Leadership transition plans

0:26:00

Wong expressed satisfaction in filling position of chair of DI Subcommittee.

- Will continue to work on transition plan and report back at next meeting.

Wong then gave floor to Ulloa for DI Subcommittee report.

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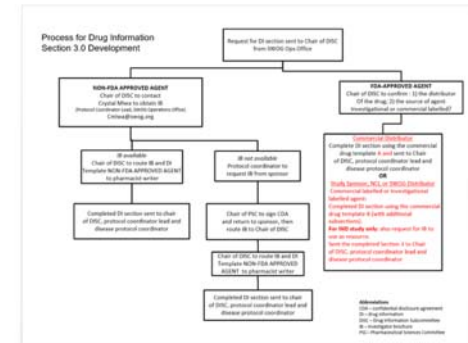
## Drug Information Subcommittee Report

0:26:26

### Approval of Drug Information Procedures and templates

Ulloa reported on the DI Subcommittee.

- Had approval for drug information procedures and templates
- Slide shows process for Section 3 development
  - Algorithm for identifying which type of template to use
  - Can be FDA-approved agent or non-FDA-approved
- For FDA-approved, two templates:
  - Template A: Drug from commercial distributor
  - Template B: Drug from study sponsor, NCI, or SWOG distributor



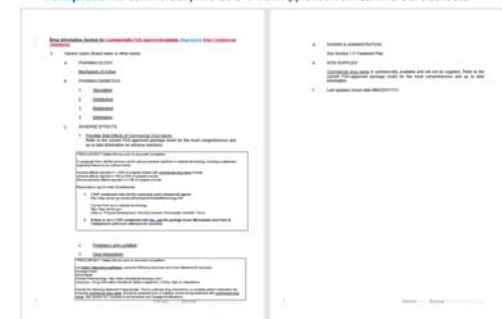
0:27:34

Ulloa highlighted main changes in each template.

Template A:

- Wording changed from “commercially available” to “FDA-approved from commercial distributor”

Template A: Commercially Available → FDA-Approved from Commercial Distributor

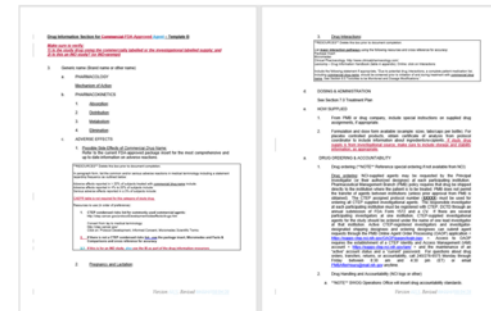


0:27:54

Template B:

- Wording changed from “commercial drug” to “FDA-approved agent” for study drugs from sponsor, NCI, or SWOG distributor
- Other changes also made, as visible in slide

Template B: Commercial Drug → FDA-approved Agent from Study Sponsor, NCI and SWOG

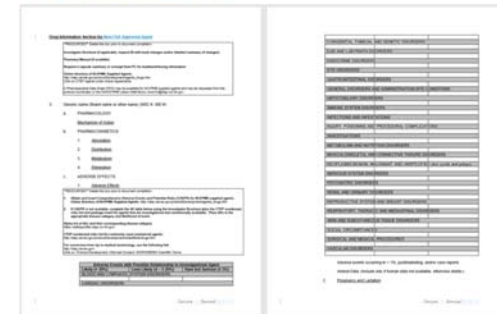


0:28:17

Non-FDA-approved template:

- Wording changed from “investigational agent” to “non-FDA-approved agent”

Non-FDA Approved Agent: Investigational Agent → non-FDA Approved Agent



0:28:30

Templates housed in DI Subcommittee SharePoint site.

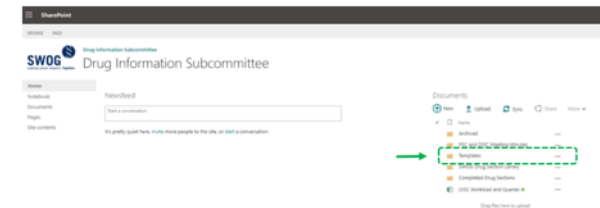
- Have been added to templates folder (see slide)

## Updates of SharePoint

0:28:40

Created small task force to reorganize and revamp SharePoint site to improve functionality.

- Ulloa expressed sincere appreciation for Crystal Miwa, Dr. Wong, and Dr. Siden for their guidance and education
- Has not been finalized, but have taken few steps forward



- Everyone in PSC should have access to this site
- Those without access should contact Ulloa to get it

Finalized templates, such as those presented, which were sent for approval to PSC are stored here in templates folder.

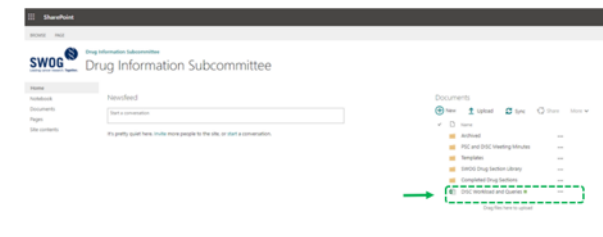
- All can be accessed from here

0:30:15

Within SharePoint were two trackers to record work done within DI Subcommittee.

There was also a query workload.

- Decided these would be easier to reference if these two were consolidated into single document
- Created a DI Subcommittee workload and queries document



0:31:01

One of workload documents that was in SharePoint now has its own tab.

- Includes information that had been in SWOG PCS protocol review spreadsheet

#### DISC Workload and Queries

- SWOG Pharma Sci Protocol Review Spreadsheet

Date of Review	Protocol	Program	Reviewer	
8/1/2018	1010	Intensiveness	Dr. [Name]	
8/1/2018	1011	Intensiveness	Dr. [Name]	
8/1/2018	1012	Intensiveness	Dr. [Name]	
8/1/2018	1013	Intensiveness	Dr. [Name]	
8/1/2018	1014	Intensiveness	Dr. [Name]	
8/1/2018	1015	Intensiveness	Dr. [Name]	
8/1/2018	1016	Intensiveness	Dr. [Name]	
8/1/2018	1017	Intensiveness	Dr. [Name]	
8/1/2018	1018	Intensiveness	Dr. [Name]	
8/1/2018	1019	Intensiveness	Dr. [Name]	
8/1/2018	1020	Intensiveness	Dr. [Name]	
8/1/2018	1021	Intensiveness	Dr. [Name]	
8/1/2018	1022	Intensiveness	Dr. [Name]	
8/1/2018	1023	Intensiveness	Dr. [Name]	
8/1/2018	1024	Intensiveness	Dr. [Name]	
8/1/2018	1025	Intensiveness	Dr. [Name]	
8/1/2018	1026	Intensiveness	Dr. [Name]	
8/1/2018	1027	Intensiveness	Dr. [Name]	
8/1/2018	1028	Intensiveness	Dr. [Name]	
8/1/2018	1029	Intensiveness	Dr. [Name]	
8/1/2018	1030	Intensiveness	Dr. [Name]	
8/1/2018	1031	Intensiveness	Dr. [Name]	
8/1/2018	1032	Intensiveness	Dr. [Name]	
8/1/2018	1033	Intensiveness	Dr. [Name]	
8/1/2018	1034	Intensiveness	Dr. [Name]	
8/1/2018	1035	Intensiveness	Dr. [Name]	
8/1/2018	1036	Intensiveness	Dr. [Name]	
8/1/2018	1037	Intensiveness	Dr. [Name]	
8/1/2018	1038	Intensiveness	Dr. [Name]	
8/1/2018	1039	Intensiveness	Dr. [Name]	
8/1/2018	1040	Intensiveness	Dr. [Name]	
8/1/2018	1041	Intensiveness	Dr. [Name]	
8/1/2018	1042	Intensiveness	Dr. [Name]	
8/1/2018	1043	Intensiveness	Dr. [Name]	
8/1/2018	1044	Intensiveness	Dr. [Name]	
8/1/2018	1045	Intensiveness	Dr. [Name]	
8/1/2018	1046	Intensiveness	Dr. [Name]	
8/1/2018	1047	Intensiveness	Dr. [Name]	
8/1/2018	1048	Intensiveness	Dr. [Name]	
8/1/2018	1049	Intensiveness	Dr. [Name]	
8/1/2018	1050	Intensiveness	Dr. [Name]	
8/1/2018	1051	Intensiveness	Dr. [Name]	
8/1/2018	1052	Intensiveness	Dr. [Name]	
8/1/2018	1053	Intensiveness	Dr. [Name]	
8/1/2018	1054	Intensiveness	Dr. [Name]	
8/1/2018	1055	Intensiveness	Dr. [Name]	
8/1/2018	1056	Intensiveness	Dr. [Name]	
8/1/2018	1057	Intensiveness	Dr. [Name]	
8/1/2018	1058	Intensiveness	Dr. [Name]	
8/1/2018	1059	Intensiveness	Dr. [Name]	
8/1/2018	1060	Intensiveness	Dr. [Name]	
8/1/2018	1061	Intensiveness	Dr. [Name]	
8/1/2018	1062	Intensiveness	Dr. [Name]	
8/1/2018	1063	Intensiveness	Dr. [Name]	
8/1/2018	1064	Intensiveness	Dr. [Name]	
8/1/2018	1065	Intensiveness	Dr. [Name]	
8/1/2018	1066	Intensiveness	Dr. [Name]	
8/1/2018	1067	Intensiveness	Dr. [Name]	
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8/1/2018	1069	Intensiveness	Dr. [Name]	
8/1/2018	1070	Intensiveness	Dr. [Name]	
8/1/2018	1071	Intensiveness	Dr. [Name]	
8/1/2018	1072	Intensiveness	Dr. [Name]	
8/1/2018	1073	Intensiveness	Dr. [Name]	
8/1/2018	1074	Intensiveness	Dr. [Name]	
8/1/2018	1075	Intensiveness	Dr. [Name]	
8/1/2018	1076	Intensiveness	Dr. [Name]	
8/1/2018	1077	Intensiveness	Dr. [Name]	
8/1/2018	1078	Intensiveness	Dr. [Name]	
8/1/2018	1079	Intensiveness	Dr. [Name]	
8/1/2018	1080	Intensiveness	Dr. [Name]	
8/1/2018	1081	Intensiveness	Dr. [Name]	
8/1/2018	1082	Intensiveness	Dr. [Name]	
8/1/2018	1083	Intensiveness	Dr. [Name]	
8/1/2018	1084	Intensiveness	Dr. [Name]	
8/1/2018	1085	Intensiveness	Dr. [Name]	
8/1/2018	1086	Intensiveness	Dr. [Name]	
8/1/2018	1087	Intensiveness	Dr. [Name]	
8/1/2018	1088	Intensiveness	Dr. [Name]	
8/1/2018	1089	Intensiveness	Dr. [Name]	
8/1/2018	1090	Intensiveness	Dr. [Name]	
8/1/2018	1091	Intensiveness	Dr. [Name]	
8/1/2018	1092	Intensiveness	Dr. [Name]	
8/1/2018	1093	Intensiveness	Dr. [Name]	
8/1/2018	1094	Intensiveness	Dr. [Name]	
8/1/2018	1095	Intensiveness	Dr. [Name]	
8/1/2018	1096	Intensiveness	Dr. [Name]	
8/1/2018	1097	Intensiveness	Dr. [Name]	
8/1/2018	1098	Intensiveness	Dr. [Name]	
8/1/2018	1099	Intensiveness	Dr. [Name]	
8/1/2018	1100	Intensiveness	Dr. [Name]	

Similarly, document titled drug information section workload has its own tab.

- Drug Information Section Workload

Created a new workload for requests coming in from 2020 forward.

- DISC Workload and Queries:** DIS Workload 2020-on

Here is query workload mentioned above; also now has its own tab.

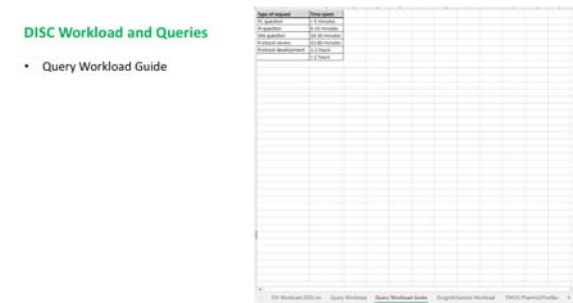
**DISC Workload and Queries:** Query Workload

Year	Release Year	Artist	Genre	Comments
1910	1910	John L. Smith	Rock	1910
1911	1911	John L. Smith	Rock	1911
1912	1912	John L. Smith	Rock	1912
1913	1913	John L. Smith	Rock	1913
1914	1914	John L. Smith	Rock	1914
1915	1915	John L. Smith	Rock	1915
1916	1916	John L. Smith	Rock	1916
1917	1917	John L. Smith	Rock	1917
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0:32:18

Also the workload guide.

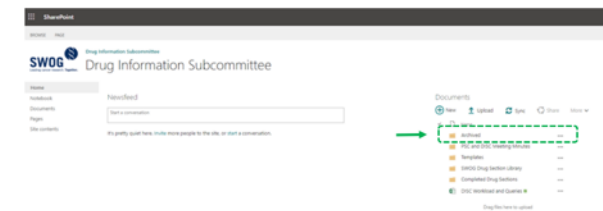
- PSC members have access and are welcome to refer to as needed



0:32:32

All documents consolidated into the workload and queries document now live in Archived folder.

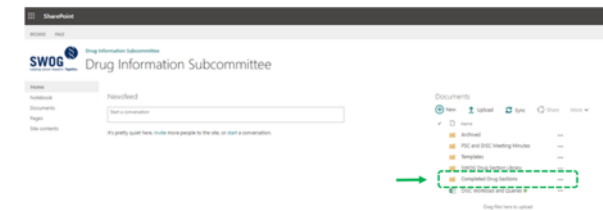
- Could live here for couple of months until they determine whether consolidation was a good idea



0:33:03

Another folder is Completed Drug Sections.

- Stores all DI sections that have been finalized
- For now, please send finalized DI sections to Ulloa so she can log into tracker and store in this folder
- Ulloa wants to ensure that folder organization is as functional as possible before sharing direct access for submitting and placing finalized DI sections
- In short, please send to Ulloa for now



0:34:20

Meeting Minutes folder stores minutes of previous meetings, and today's meeting minutes will be there.

Wong asked Ulloa or Miwa to explain difference between folders SWOG Drug Section Library and Completed Drug Sections.

- Ulloa noted SWOG Drug Section Library holds PI sections that have already gone through CTEP review and come back
  - Have not yet decided these documents will stay there
  - Will let the PSC know once they finalize SharePoint

Wong confirmed the following with Ulloa:

- Completed Drug Sections is PSC-completed sections that will be submitted to Ops Office
- Protocol coordinators place final form, after final review by everyone, in SWOG Drug Section Library
- PSC members asked to write and who want to get an update for a DI section should go to SWOG Drug Section Library

Wong asked whether Ulloa wanted members to come into SharePoint and pick drug section to update from that folder.

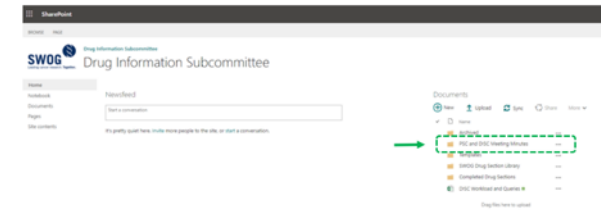
- Ulloa and Miwa said they were still working on process and would continue discussion

Wong asked whether, when updates are needed, Ulloa will provide writer most recent version of Section 3 to work on.

- Miwa said this is probably the easiest method right now because protocols are final versions
  - That version normally has protocol-specific information as well

Wong noted writers were on the call and confirmed they should ask Ulloa and Miwa for sections for now, until SharePoint is fully set up.

- Miwa confirmed this





- Said her process when providing a requested submission is to include drug section and any other relevant material that could be used for it

Rivka Siden reaffirmed Miwa's words:

- Usually Ops Office provides latest version of Section 3 to work on in response to requests

---

#### *Updates of PSC manual*

0:39:25

Ulloa noted that documents to be stored within SharePoint are those that change frequently.

- However, there are other documents that are more durable
- Those will live on the website and are more widely accessible
- These will be part of PSC manual
- Some documents being updated that will be incorporated into the website

---

#### **Drug information activities updates**

0:40:50

Ulloa said DI Subcommittee had had 9 write-up requests—for the following:

- ramucirumab
- encorafenib
- binimetinib
- sacituzumab govitecan
- ibrutinib
- AMG510
- avelumab
- entecavir
- tenofovir disoproxil

Ulloa thanked all writers and reviewers for time put into these sections.

---

#### **Feedback from Drug Information Residents/Program Directors**

0:41:38

Ulloa extended special thanks to drug information residents and their program directors, Kim Redic and Janet Mighty

- Invited feedback from these residents and program directors

Wong noted Redic and Mighty were not on call. Resident Michelle Yu spoke.

- Yu said she had experienced only one assignment thus far
- Went smoothly
- Wong had provided wonderful introduction to committee and responsibilities of residents

Wong asked whether activity had enriched Yu's training or committee could take other steps to enrich her residency.

- Yu said residency had gone well
- Had never been called on to write something of the sort before
- Thought it would be interesting to see rest of protocol and how drug information section fits into it

Wong said she would bring Yu in next time committee was called on to review a protocol.

Ulloa thanked Drs. Smith and Yu, the residents working on two latest requests.

---

### **Protocol review activities**

0:44:52

Ulloa introduced Drs. Chan and Avila.

Holly Chan noted she works with Jorge Avila on protocol reviews.

- Said Jorge generally gets requests for protocol review for solid tumors
  - She gets requests for hematologic malignancies—myeloma, lymphomas, and leukemias
  - They then recruit disease committee liaison to conduct the review
-

- Thus far this year review requests in hematology have been few

---

**Drug interaction initiative updates**

0:46:04

Ulloa introduced Dan Hertz.

Wong said she does not see Hertz's name on list of callers. He had said he might not be able to attend entire session. Suggested group move to next item and return to Hertz when he joins the call.

---

## Study Drug Handling and Patient Education Handout follow-up

0:46:47

Wong discussed item previously raised by Ops Office: wallet card patient education handout.

- Asked Abueg if plan was to reach out to partner with ORP Committee on creating these documents
- Abueg said yes
- She briefly spoke about Hertz's drug interaction initiative update, from ORP perspective
  - ORP Committee was going to invite Hertz to be part of Oishi Symposium this year, but symposium has gone to a virtual format that significantly shortened available time
  - Decided to invite Hertz for Spring meeting instead
- Re drug handling handout: much opportunity for ORP to partner
  - Particularly as ORP just got notice from PMB that mailing of drugs will be extended through May 2021 because of COVID
  - So there are many opportunities to employ this handout
  - Abueg is now education coordinator for ORP Cmte
  - Opportunity for ORP to promote handout; she will discuss it in next day's ORP session on adapting to COVID when running trials
  - Will include discussion of mailing drugs to patients
  - Many sites will be interested
  - Big questions would be
    - IRB approval
    - CIRB approval
    - Where to house it

Wong noted that patient education handout idea had been raised by PSC but was turned down

- Thinks concern was ability to keep it updated and IRB-approved
  - CIRB concept brought up at last meeting by Dr. Meyskens
  - Would this address concerns that were raised?
-

- Hoped that ORP Cmte would discuss and Abueg could bring issue back to PSC with next steps
-

## **BEACON standardized orderset updates**

0:51:56

Wong introduced Jane Rogers.

Rogers said there was no update on the BEACON orderset.

- Protocol it's being piloted on requires changes before activation
- Expect activation in October or November

Wong reminded Rogers that PSC members have expressed interest in working on this.

- Asked that if other requests for protocols for this come in, Rogers engage these members
- Rogers acknowledged they will want feedback from PSC members on issue before extending to new protocols
- Noted she would update group soon on this topic

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## **Digital Engagement Committee**

0:53:28

Wong noted Hertz was not on call, so this item would be skipped.

- In her last conversation with him, she does not have significant news to report on this topic
-

## Committee webpage on SWOG website

0:53:42

Wong asked Siden, as originator of PSC webpage, to report on this ([Appendix B](#)).

Siden noted she copied information from the website for the slide.

- PSC site lives on SWOG website under Pharmaceutical Sciences
- Title is Pharmaceutical Resources
- Opens with statement of committee mission, followed by list of leadership with photo of Wong as chair
- Then lists PSC liaisons to other committees
  - Should be updated each time list is changed
- Lists of resources follow, starting with training resources
  - Active links that take visitor to various resources
- Next section is resources for protocol review and investigational drugs
- Audit checklist created with committee is also provided
- Next section is thorough, comprehensive collection of pharmacogenomic resources
- Following section is new member resources, including first-time meeting guide for pharmacists
  - Geared to first-time participation in live meeting
  - Siden hoped these would be resumed
- Last document is new member packet
  - Will need to be updated (as mentioned by Ulloa)
  - Includes protocol review process, drug info Section 3 writing process, and other committee processes
- SharePoint resources also given

Siden suggested next step would be having a PSC volunteer to update site regularly.

- Years ago, on old website, documents sent after every meeting
- When they moved to new site, included only documents that don't need as much updating

## Pharmaceutical Resources

SWOG Cancer Research Network's Pharmaceutical Sciences Committee is the group's source of drug expertise. They provide members with information and training on investigational drug handling, interactions, quality control, and more. They also provide SWOG committees with guidance on protocol development, patient education, and key topics such as pharmacogenomics.

### Committee Leadership

Pharmaceutical Sciences Co-Chair  
Siu-Fun Wong, PharmD, [FASHP](#), [FCSHP](#) [sfwong@chapman.edu](mailto:sfwong@chapman.edu)  
Drug Information Chair  
Aida Ulloa, PhD [Aida.Ulloa@uchealth.org](mailto:Aida.Ulloa@uchealth.org)

### Committee Pharmacist Liaisons

BREAST  
Primary Liaison Jessie Modlin, PharmD [modlinj@sihs.org](mailto:modlinj@sihs.org)  
Secondary Liaison Jorge Avila [Jorge.Avila@moffitt.org](mailto:Jorge.Avila@moffitt.org)  
CANCER CONTROL  
Primary Liaisons Coco Yang, BS Pharm PhD [syang@chapman.edu](mailto:syang@chapman.edu) & Kimberly McConnell, PharmD [kamcconnell@ucsd.edu](mailto:kamcconnell@ucsd.edu)  
Secondary Liaison Siu-Fun Wong [sfwong@chapman.edu](mailto:sfwong@chapman.edu)  
EARLY THERAPEUTICS  
Primary Liaison Craig Elg, PharmD [Craig.X.Elga@kp.org](mailto:Craig.X.Elga@kp.org)  
Secondary Liaison Coco Yang, BS Pharm PhD [syang@chapman.edu](mailto:syang@chapman.edu)

[etc.](#)

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### Training Resources

SWOG's Investigational Drug Handling course can be found [here](#).  
NCI's Pharmaceutical Management Branch Investigational Drug Accountability video tutorials can be viewed [here](#).

### Protocol & Safety Resources

[SWOG Investigational Agent Audit Checklist](#)  
[SWOG Protocol Review Guidelines Checklist](#)

- Volunteer would work with Ulloa on things such as updating minutes after meetings

Wong noted that first-time meeting guide for pharmacists was created by Linda Lee, former chair of DI Subcommittee.

- PSC typically does in-person orientation for PSC members attending their first group meeting
- Hoped PSC would be able to resume this by next year

Frank Meyskens asked about standardization procedures for set of different molecules, large area of biosimilars, pharmacogenomics, and immunologicals that is exploding.

- Will there be, and how, standardization of this language as has been done for more conventional things?

Wong noted that for biosimilars PSC has a statement in place they recommended to SWOG.

- Currently all biosimilars are considered as equivalents
- PSC language says institutions can use biosimilars as they see fit unless protocol specifies otherwise
- Term used in past was “interchangeable,” but because now they are all considered interchangeable, utility of term is no longer emphasized
- Last time PSC reviewed this was about a year ago

RE genomics: Wong said they have not explored much

- Used to have a genomics expert as cochair of PSC
- Appears there is a preference for genomics to be led by other entity in SWOG
- Also, there are not many standardized guidelines, and there have not been many requests engaging PSC in this area
- So PSC has not spent much time reviewing this
- Nonetheless, given new DI Subcommittee chair Ulloa’s PhD training, perhaps PSC can revisit this once Ulloa has completed her current projects, if there is a need

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[SWOG Biosimilars Guidelines](#)  
[NCI Pharmaceutical Management Branch website](#)  
[NCI Cancer Therapy Evaluation Program \(CTEP\) forms, templates, and documents](#)  
[NCI CTEP Tables of Possible Side Effects in Commonly Used Drugs](#)  
[NCI Audit Guidelines](#)

#### Pharmacogenomic Resources

Food and Drug Administration [Table of Pharmacogenomic Biomarkers in Drug Labeling](#)  
[NIH Database of Genotypes and Phenotypes \(dbGaP\)](#)  
[The Pharmacogenomics Knowledgebase](#)  
[NIH Genotype-Tissue Expression \(GTEx\)](#)  
[The Evaluation of Genomic Applications in Practice and Prevention \(EGAPP\)](#)  
[PGRN: Pharmacogenomics Research Network](#)  
[The Genetics/Genomics Competency Center \(G2C2\)](#)  
[G2C2 Online Collection of Materials for Self-Directed Learning](#)

#### New Member Resources

[First Time Meeting Guide for Pharmacists](#)  
[New Member Packet](#)

#### SharePoint-under review and revision (Aida)

1. Meeting minutes (needs updating after each meeting)
  2. Drug monograph templates
  3. Drug Sections Library (these are the FINAL Sections- discussing how to manage?)
  4. Pending Drug Sections (will not continue to use)
  5. Completed Drug Sections
  6. Drug information section workload; Protocol review spreadsheet; Query workload- combined
  7. Activities and responsibilities – will combine with New Member Packet?
-



- Meyskens suspected there will be a need, given the complexity of subject and the acronyms; thanked Wong for response
  - Ulloa agreed subject is exploding and creating need
    - Great tool but it's complexity can lead to reluctance to use it
-

## Pharmacist liaison reports

1:05:12

Wong asked Miwa to share liaison list on screen ([Appendix C](#)).

- Wong updated list Sept 22
- Noted that Jessie Modlin, a long-time member, because of demands of practice would no longer be able to serve as PSC liaison to Breast Committee
  - Anyone interested, please let Wong know
  - Very active committee, so could use two liaisons
- Thanked those who volunteered for these roles after last virtual meeting
- Anyone wanting to switch committees should let Wong know
- List is quite healthy, apart from open slot in Breast Committee
- Hopes to have it filled by next meeting

**SWOG Pharmacist Liaison (PL) Assignments (updated 09.22.2020)**  
 SWOG Group Chair's Office (OHSU, OR): 503-494-5566; Operations Office (San Antonio, TX): 210-614-8808; Statistical Center (Seattle, WA): 206-632-2267  
 Committee Chair: [Bilal Wong](#) ([bwong@hsa.usf.edu](#)); Drug Information Subcommittee Chair: [Ulrich, Aida](#) ([Aida.Ulrich@ucsf.edu](#)); PC Liaison: [Crystal Miwa](#) ([Cmiwa@hsa.usf.edu](#))

Disease Committee	Primary PL	Secondary PL	Protocol Coordinator	Committee Leaders
Breast		Jorge Avila <a href="#">jorge.avila@hsa.usf.edu</a>	Sara Leubech <a href="#">sleubech@hsa.usf.edu</a>	Laura Pusde, MD (Chair)
Cancer Control	Kimberly McConnell <a href="#">kmcconnell@hsa.usf.edu</a>	Siu-Fun Wong <a href="#">sfwong@hsa.usf.edu</a>	Veronica Garcia (Sunriseville) <a href="#">vgarcia@hsa.usf.edu</a>	Dawn Hershman <a href="#">Dhershman@hsa.usf.edu</a>
			Bonnie Tinsley (SCQOL) <a href="#">btinsley@hsa.usf.edu</a>	
			Patricia O'Kane <a href="#">pokane@hsa.usf.edu</a>	
GI	Jane Rogers <a href="#">jrogers@hsa.usf.edu</a>	Jason Reed <a href="#">jreed@hsa.usf.edu</a>	Danai Campos <a href="#">dcampos@hsa.usf.edu</a>	Philip A. Philis, MD, PhD <a href="#">philis@hsa.usf.edu</a>
Early Therapeutics	Craig Ely <a href="#">cely@hsa.usf.edu</a>	Cao Yang <a href="#">caoyang@hsa.usf.edu</a>	Orinay Kappela <a href="#">okappela@hsa.usf.edu</a>	Razelle Kurzrock, MD
GU	Jhyot Lee <a href="#">jlee@hsa.usf.edu</a>	Jason Reed <a href="#">jreed@hsa.usf.edu</a>	Veronica Garcia <a href="#">vgarcia@hsa.usf.edu</a>	Ben M. Thompson, MD <a href="#">bthompson@hsa.usf.edu</a>
Leukemia + BMT	Holly Chan <a href="#">hchan@hsa.usf.edu</a>	Ila Saunders <a href="#">isaunders@hsa.usf.edu</a>	WBO (interim) Drethien Goetz <a href="#">dgoetz@hsa.usf.edu</a>	Harry Eda, MD, PhD <a href="#">harry.eda@hsa.usf.edu</a>
Lung	Jhyot Lee <a href="#">jlee@hsa.usf.edu</a>	Kimberly McConnell <a href="#">kmcconnell@hsa.usf.edu</a>	Uneshen Goetz <a href="#">ugoetz@hsa.usf.edu</a>	Karen Kelly <a href="#">kkelly@hsa.usf.edu</a>
Lymphoma	Holly Chan <a href="#">hchan@hsa.usf.edu</a>	Al McBride <a href="#">al.mcbride@hsa.usf.edu</a>	Lung-MAP: Mariah Norman, Laura Gishner <a href="#">norman@hsa.usf.edu</a> / <a href="#">lgishner@hsa.usf.edu</a>	Jonathan Friedberg, MD <a href="#">jfriedberg@hsa.usf.edu</a>
Melanoma	Cao Yang <a href="#">caoyang@hsa.usf.edu</a>	Danai Campos <a href="#">dcampos@hsa.usf.edu</a>		Amrith Bhat, MD <a href="#">abhat@hsa.usf.edu</a>
Myeloma	Craig Ely <a href="#">cely@hsa.usf.edu</a>	Ila Saunders <a href="#">isaunders@hsa.usf.edu</a>	WBO (interim) Drethien Goetz <a href="#">dgoetz@hsa.usf.edu</a>	Robert Onowski, MD, PhD <a href="#">ronowski@hsa.usf.edu</a>

Wong asked whether any liaisons had reports or recommendations.

1:07:48

Wong posted slide of the PSC membership list ([Appendix D](#)).

- Asked attendees to review list for correctness and completeness and send her updates as needed
- Noted that some names on list may be unknown to many attendees; some members because of practices are not able to engage as fully with PSC, but committee welcomes them as potentially offering valuable input
- Wong said goal is to keep membership as diverse as possible
  - In providing support to SWOG, PSC also needs to consider diversity of investigational site
- Other members are seen as honorary members because of their accomplishments or their input at creation of committee or in oncology research

Southwest Oncology Group Statistical Center  
 Committee ID: P1A0H  
 (\* = Working Group Member)

name	prof	inv	spec	glsc	comm	role	lname	noi=
Wong, Siu-Fun	PharmD	SC	FIARH	CSAIA	Chapman University	EPIC		grat
Abung, Kristine D.	MD, MEd				Kaiser Perm NCCRP	NCCRP		
Au, Sara H.	PharmD	SC	FIARH	MDH	Hawaii, MD-NCCRP	NCCRP		
Avila, Jorge G.	PharmD	SC	FIARH	MDH	H Lee Moffitt CC	MDH		
Chan, Holly O.	PharmD	SC	FIARH	MDH	City of Hope Med Ctr	MDH		
Chang, Christine H.	MD	MD	ORC	MDH	H Lee Moffitt CC	MDH		
Denison, Sharon R.	PharmD	SC	FIARH	MDH	City of Hope Med Ctr	MDH		
Ely, Craig	PharmD				Pharm Liaison: ETS &			
Foreman, Noel A.	PharmD				Rochester, Univ of			
Hertz, Daniel L.	PharmD, PhD	SC	FIARH	MDH	Michigan, U of	MDH		
Kerr, Julia R.	PharmD	SC	FIARH	MDH	St Luke's Mt State	NCCRP		
Kubo, John G.	PharmD							
Lee, Joyce	PharmD				Davis, U of CA	MDH		
Liu, Chin Y.	PharmD	SC	FIARH	MDH	Wayne State Univ	MDH		
Melara, Makenzie P.	MD				H Lee Moffitt CC			
Marcath, Lauren A.	PharmD	SC	FIARH	MDH	Michigan, U of	MDH		
Martin, Oscar D.	PharmD	SC	FIARH	MDH	City of Hope Med Ctr	MDH		
McBride, Ali	PharmD	SC	FIARH	MDH	Arizona CC, Univ of	MDH		
McConnell, Kimberly	PharmD				San Diego, U of CA	MDH		
Modlin, Jessie	PharmD				St Luke's Mt State	NCCRP		
Nguyen, Mai T.	PharmD				Oklahoma, Univ of	MDH		
Patel, Bhambini	PharmD							
Reed, Jason M.	PharmD, RPh				MD Anderson CC	MDH		
Rogers, Jane E.	PharmD	SC	FIARH	MDH	MD Anderson CC	MDH		
Saunders, Ila M.	PharmD	SC	FIARH	MDH	San Diego, U of CA	MDH		
Saunders, Jacqueline A.	PharmD	SC	FIARH	MDH	Johns Hopkins Univ	EPIC		
Yang, Sun	PharmD, PhD	SC	FIARH	MDH	Chapman University	EPIC		
Yu, Michelle	MS, PharmD	SC	FIARH	MDH	Johns Hopkins Univ	EPIC		

28 rows selected.

Siden asked if this was the complete list.

- Noted her name was not listed
  - Wong said she would remedy this

- Siden said she had just heard from Dan Hertz that he was teaching a class at the moment and was thus unable to attend current meeting
- Wong said as far as she knew for the DI, Hertz was trying to get a multicenter study going
  - After completion of that, next step for PSC will be to broaden evaluation of drug interaction platform group has been developing

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1:11:13

Wong noted group had reached end of its agenda and asked whether attendees had items to bring up.

- Highlighted PSC is a service committee, and thanked group for hard work
- Hoped for in-person opportunities soon, in spite of her gut feeling things would turn out otherwise

1:13:00

Wong adjourned meeting.

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## APPENDIX A: SWOG Protocol Drug Interaction Standardized

### Section 3 Drug Information

Drug Interactions:

Concomitant administration of [“Study Drug”] with inhibitors/inducers of [e.g. CYP, UGT1A1, p-gp] may alter the pharmacokinetic or pharmacodynamics properties of the [“Study Drug”]. See Section 7.X for details.

### Section 7 Treatment Plan

*Please select the appropriate option(s) and select/fill in the information in the [ ] as appropriate, plus the respective reference listing(s):*

[“Study Drug”] is a substrate of enzyme (e.g. CYP#X#, UGT1A1). Concurrent administration of the strong/moderate inhibitors or inducers of the enzyme [should be avoided during study participation]/ [warrant trial exclusion] to avoid increased or decreased systemic exposure of the [“Study Drug”].

[“Study Drug”] is a strong/moderate inhibitor of enzyme (e.g. CYP#X#, UGT1A1). Concurrent administration of the enzyme substrates [should be avoided during study participation]/ [warrant trial exclusion] to avoid increased systemic exposure of the substrates.

[“Study Drug”] is a strong/moderate inducer of enzyme (e.g. CYP#X#, UGT1A1). Concurrent administration of the enzyme substrates [should be avoided during study participation]/ [warrant trial exclusion] to avoid decreased systemic exposure of the substrates.

Lists of CYP3A4 inhibitors or inducers are accessible from:

<https://drug-interactions.medicine.iu.edu/MainTable.aspx> OR consult local institutional pharmacists.

Lists of common UGT1A1 substrates are accessible from:

<https://www.drugbank.ca/unearth/q?utf8=%E2%9C%93&searcher=drugs&query=UGT1A1+substrate> OR consult local institutional pharmacists.

Lists of common UGT1A1 inhibitors are accessible from: <https://www.drugbank.ca/categories/DBCAT002664> OR consult local institutional pharmacists.

Lists of common UGT1A1 inducers are accessible from: <https://www.drugbank.ca/categories/DBCAT003925> OR consult local institutional pharmacists.

["Study Drug"] is a substrate of transporter [e.g. P-gp, BCRP, OATP1B1 or 3, OAT1 or 3, MATE1 or 2K, OCT2]. Concurrent administration of the inhibitors or inducers of the transporter [should be avoided during study participation]/ [warrant trial exclusion] to avoid increased or decreased systemic exposure of the ["Study Drug"].

["Study Drug"] is an inhibitor of transporter [e.g. P-gp, BCRP, OATP1B1 or 3, OAT1 or 3, MATE1 or 2K]. Concurrent administration of the transporter substrates [should be avoided during study participation]/ [warrant trial exclusion] to avoid increased systemic exposure of the substrates.

Examples of clinical substrates and inhibitors of transporters [e.g. P-gp, BCRP, OATP1B1 or 3, OAT1 or 3, MATE1 or 2K, OCT2] are accessible from:  
<https://www.fda.gov/drugs/drug-interactions-labeling/drug-development-and-drug-interactions-table-substrates-inhibitors-and-inducers> OR consult local institutional pharmacists.

["Study Drug"] can [cause QT interval prolongation and ventricular arrhythmia]/[increase QT prolongation risk of concomitant drugs]. Concurrent administration of these agents [should be avoided during study participation]/ [warrant trial exclusion].  
Lists of drugs known to have QT prolongation risk are accessible from (requires free registration):  
<https://www.crediblemeds.org/> OR consult local institutional pharmacists.

## APPENDIX B: Pharmaceutical Sciences Committee Web Page on SWOG Website

### Pharmaceutical Resources

SWOG Cancer Research Network's Pharmaceutical Sciences Committee is the group's source of drug expertise. They provide members with information and training on investigational drug handling, interactions, quality control, and more. They also provide SWOG committees with guidance on protocol development, patient education, and key topics such as pharmacogenomics.

#### Committee Leadership

##### Pharmaceutical Sciences Co-Chair

Siu-Fun Wong, PharmD, FASHP, FCSHP [sfwong@chapman.edu](mailto:sfwong@chapman.edu)

##### Drug Information Chair

Aida Ulloa, PhD [Aida.Ulloa@uchealth.org](mailto:Aida.Ulloa@uchealth.org)

#### Committee Pharmacist Liaisons

##### BREAST

Primary Liaison Jessie Modlin, PharmD [modlinj@slhs.org](mailto:modlinj@slhs.org)

Secondary Liaison Jorge Avila [Jorge.Avila@moffitt.org](mailto:Jorge.Avila@moffitt.org)

##### CANCER CONTROL

Primary Liaisons Coco Yang, BS Pharm PhD [syang@chapman.edu](mailto:syang@chapman.edu) & Kimberly McConnell, PharmD [kamcconell@ucsd.edu](mailto:kamcconell@ucsd.edu)

Secondary Liaison Siu-Fun Wong [sfwong@chapman.edu](mailto:sfwong@chapman.edu)

##### EARLY THERAPEUTICS

Primary Liaison Craig Elg, PharmD [Craig.X.Elg@kp.org](mailto:Craig.X.Elg@kp.org)

Secondary Liaison Coco Yang, BS Pharm PhD [syang@chapman.edu](mailto:syang@chapman.edu)

etc

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#### Training Resources

SWOG's Investigational Drug Handling course can be found [here](#).

NCI's Pharmaceutical Management Branch Investigational Drug Accountability video tutorials can be viewed [here](#).

## **Protocol & Safety Resources**

[SWOG Investigational Agent Audit Checklist](#)

[SWOG Protocol Review Guidelines Checklist](#)

[SWOG Biosimilars Guidelines](#)

NCI Pharmaceutical Management Branch [website](#)

NCI Cancer Therapy Evaluation Program (CTEP) [forms, templates, and documents](#)

NCI CTEP [Tables of Possible Side Effects in Commonly Used Drugs](#)

NCI [Audit Guidelines](#)

## **Pharmacogenomic Resources**

Food and Drug Administration [Table of Pharmacogenomic Biomarkers in Drug Labeling](#)

NIH [Database of Genotypes and Phenotypes](#) (dbGaP)

The [Pharmacogenomics Knowledgebase](#)

NIH [Genotype-Tissue Expression](#) (GTEx)

The [Evaluation of Genomic Applications in Practice and Prevention](#) (EGAPP)

PGRN: [Pharmacogenomics Research Network](#)

The [Genetics/Genomics Competency Center](#) (G2C2)

G2C2 [Online Collection of Materials for Self-Directed Learning](#)

## **New Member Resources**

[First Time Meeting Guide for Pharmacists](#)

[New Member Packet](#)

## **SharePoint-under review and revision (Aida)**

1. Meeting minutes (needs updating after each meeting)
2. Drug monograph templates
3. Drug Sections Library (these are the FINAL Sections- discussing how to manage?)
4. Pending Drug Sections (will not continue to use)
5. Completed Drug Sections
6. Drug information section workload; Protocol review spreadsheet; Query workload- combined
7. Activities and responsibilities – will combine with New Member Packet?

## Appendix C: SWOG Pharmacist Liaison Assignments

### SWOG Pharmacist Liaison (PL) Assignments (updated 09.22.2020)

SWOG Group Chair's Office (OHSU, OR): 503-494-5586; Operations Office (San Antonio, TX): 210-614-8808; Statistical Center (Seattle, WA):206-652-2267

Committee Chair: SiuFun Wong [sfwong3@hs.uci.edu](mailto:sfwong3@hs.uci.edu); Drug Information Subcommittee Chair: Ulloa, Aida <[Aida.Ulloa@uhealth.org](mailto:Aida.Ulloa@uhealth.org)>. PC Liaison: Crystal Miwa [CMiwa@swog.org](mailto:CMiwa@swog.org)

Disease Committee	Primary PL	Secondary PL	Protocol Coordinator	Committee Leaders
Breast		Jorge Avila <a href="mailto:Jorge.Avila@moffitt.org">Jorge.Avila@moffitt.org</a>	Cara Laubach <a href="mailto:claubach@swog.org">claubach@swog.org</a>	Lajos Puzstai, MD (Chair)
Cancer Control	Kimberly Mcconnell <a href="mailto:kamcconnell@ucsd.edu">kamcconnell@ucsd.edu</a>	Siu-Fun Wong <a href="mailto:sfwong3@hs.uci.edu">sfwong3@hs.uci.edu</a>	Veronica Garcia (Survivorship) <a href="mailto:vgarcia@swog.org">vgarcia@swog.org</a>	Dawn Hershman <a href="mailto:Dlh23@columbia.edu">Dlh23@columbia.edu</a>
	Coco Yang <a href="mailto:syang@chapman.edu">syang@chapman.edu</a>		Sonali Tinsley (SCQOL) Patricia O'Kane <a href="mailto:pokane@swog.org">pokane@swog.org</a>	
GI	Jane Rogers <a href="mailto:jerogers@mdanderson.org">jerogers@mdanderson.org</a>	Jason Reed <a href="mailto:JMReed@mdanderson.org">JMReed@mdanderson.org</a>	Danae Campos <a href="mailto:dcampos@swog.org">dcampos@swog.org</a>	Philip A. Philip, MD, PhD
Early Therapeutics	Craig Elg <a href="mailto:Craig.X.Elg@kp.org">Craig.X.Elg@kp.org</a>	Coco Yang <a href="mailto:syang@chapman.edu">syang@chapman.edu</a>	Christy Klepetko <a href="mailto:cklepetko@swog.org">cklepetko@swog.org</a>	Razelle Kurzrock, MD
GU	Joyce Lee <a href="mailto:jsylee@ucdavis.edu">jsylee@ucdavis.edu</a>	Jason Reed <a href="mailto:JMReed@mdanderson.org">JMReed@mdanderson.org</a>	Veronica Garcia <a href="mailto:vgarcia@swog.org">vgarcia@swog.org</a>	Ian M. Thompson Jr., MD <a href="mailto:thompsoni@uthscsa.edu">thompsoni@uthscsa.edu</a>



Leukemia + BMT	Holly Chan <a href="mailto:hchan@coh.org">hchan@coh.org</a>	Ila Saunders <a href="mailto:isaunders@health.ucsd.edu">isaunders@health.ucsd.edu</a>	TBD (Interim) Gretchen Goetz <a href="mailto:ggoetz@swog.org">ggoetz@swog.org</a>	Harry Erba, MD, , PhD <a href="mailto:Harry.erba@ccc.uab.edu">Harry.erba@ccc.uab.edu</a>
Lung	Joyce Lee <a href="mailto:jsylee@ucdavis.edu">jsylee@ucdavis.edu</a>	Kimberly McConnell <a href="mailto:kamcconnell@ucsd.edu">kamcconnell@ucsd.edu</a>	Gretchen Goetz <a href="mailto:ggoetz@swog.org">ggoetz@swog.org</a>  Lung-MAP: Mariah Norman/Laura Gildner <a href="mailto:mnorman@swog.org">mnorman@swog.org</a> / <a href="mailto:lgildner@swog.org">lgildner@swog.org</a>	Karen Kelly <a href="mailto:karkelly@ucdavis.edu">karkelly@ucdavis.edu</a>
Lymphoma	Holly Chan <a href="mailto:hchan@coh.org">hchan@coh.org</a>	Ali McBride <a href="mailto:Ali.McBride@bannerhealth.com">Ali.McBride@bannerhealth.com</a>	Cara Laubach <a href="mailto:claubach@swog.org">claubach@swog.org</a>	Jonathan Friedberg, MD <a href="mailto:jonathanfriedberg@urmc.rochester.edu">jonathanfriedberg@urmc.rochester.edu</a>
Melanoma	Coco Yang <a href="mailto:syang@chapman.edu">syang@chapman.edu</a>		Danae Campos <a href="mailto:dcampos@swog.org">dcampos@swog.org</a>	Antoni Ribas, MD <a href="mailto:aribas@mednet.ucla.edu">aribas@mednet.ucla.edu</a>
Myeloma	Craig Elg <a href="mailto:Craig.X.Elg@kp.org">Craig.X.Elg@kp.org</a>	Ila Saunders <a href="mailto:isaunders@health.ucsd.edu">isaunders@health.ucsd.edu</a>	TBD (Interim) Gretchen Goetz <a href="mailto:ggoetz@swog.org">ggoetz@swog.org</a>	Robert Orlowski, MD, PhD <a href="mailto:rrolowsk@mdanderson.org">rrolowsk@mdanderson.org</a>

## Appendix D: Pharmaceutical Sciences Committee Membership List Fall 2020

Southwest Oncology Group Statistical Center

Committee ID: PHARM  
(\* = Working Group Member)

name	prof	inv spec	disc	comm role	instname	nci- grant
Wong, Siu-Fun	PharmD	SC	PHARM	CHAIR	Chapman University	SPEC
Abueg, Kristine D.	RN,MSN			MEM	Kaiser Perm NCORP	NCORP
Au, Lara M.	PharmD	SC	PHARM	MEM	Hawaii MU-NCORP	NCORP
Avila, Jorge G.	PharmD	SC	PHARM	MEM	H Lee Moffitt CC	MEM
Chan, Holly O.	PharmD	SC	PHARM	MEM	City of Hope Med Ctr	MEM
Chung, Christine H.	MD	MO	ONC	MEM	H Lee Moffitt CC	MEM
Denison, Sharon R.	PHARMD	SC	PHARM	MEM	City of Hope Med Ctr	MEM
Elg, Craig	PharmD			MEM	Pharm Liaison: ETx &	
Forrett, Noel A.	PharmD			MEM	Rochester, Univ of	MEM
Hertz, Daniel L.	PharmD,PhD	SC	PHARM	MEM	Michigan, U of	MEM
Kerr, Julia R.	PharmD	SC	PHARM	MEM	St Luke's Mt State	NCORP
Kuhn, John G.	PharmD			MEM		
Lee, Joyce	PharmD			MEM	Davis, U of CA	MEM
Liu, Chin Y.	PHARMD	SC	PHARM	MEM	Wayne State Univ	MEM
Malafa, Mokenge P.	MD	S	SURG	MEM	H Lee Moffitt CC	MEM
Marcath, Lauren A.	PharmD	SC	PHARM	MEM	Michigan, U of	MEM
Martin, Oscar D.	PHARMD	SC	PHARM	MEM	City of Hope Med Ctr	MEM
McBride, Ali	PharmD	SC	PHARM	MEM	Arizona CC, Univ of	MEM
McConnell, Kimberly	PharmD			MEM	San Diego, U of CA	MEM
Modlin, Jessie	PharmD			MEM	St Luke's Mt State	NCORP
Nguyen, Mai T.	PharmD			MEM	Oklahoma, Univ of	MEM
Patel, Bhamini	RPH,MS			MEM		
Reed, Jason M.	PharmD,RPh			MEM	MD Anderson CC	MEM
Rogers, Jane E.	PharmD	SC	PHARM	MEM	MD Anderson CC	MEM
Saunders, Ila M.	PharmD	SC	PHARM	MEM	San Diego, U of CA	MEM
Saunders, Jacqueline A.	PharmD	SC	PHARM	MEM	Johns Hopkins Univ	SPEC
Yang, Sun	PharmD,PhD	SC	PHARM	MEM	Chapman University	SPEC
Yu, Michelle	BSE,PharmD	SC	PHARM	MEM	Johns Hopkins Univ	SPEC

28 rows selected.