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Managing Enterprise Clinical Trial Listings with OnCore SIP

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UF Organizational Background

- Academic Medical Center with a Cancer Center (non-designated)
- Cancer Center began using OnCore in 2009
- UF began enterprise expansion of OnCore in fall of 2017
  - expansion to be completed in 2019

What is OnCore SIP?

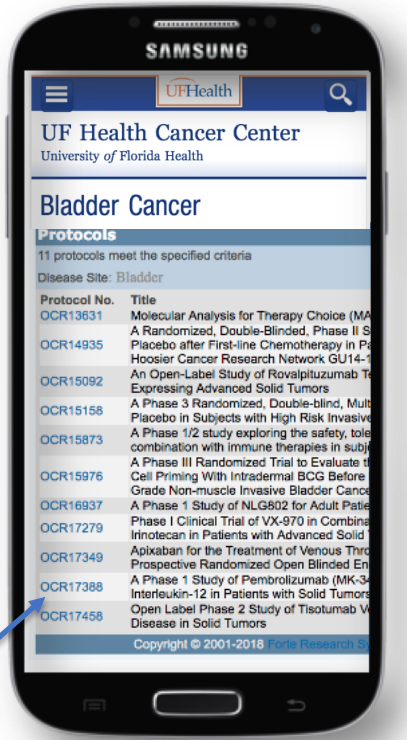
- Search engine for Active Clinical Trials – powered by OnCore
- Uses standard OnCore data
  - Protocol Title
  - PI Name
  - Phase
- Uses “SIP-specific” data from SIP Console
  - Study Objective
  - Treatment details
  - Study Description
  - Eligibility
- Can be used “out of the box” or can be customized

Historical SIP Content Management

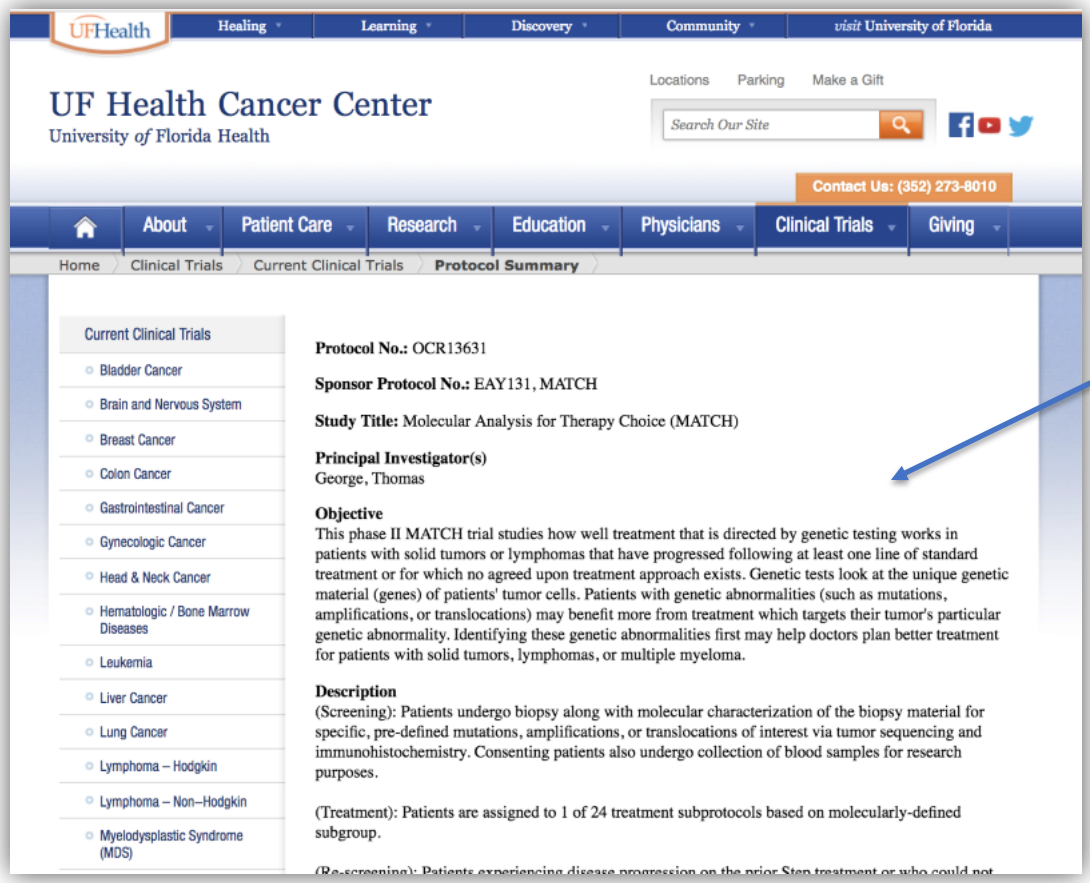
- Central management of SIP Console records (Cancer Center)
- Protocols linked to custom Web Descriptions in SIP
  - e.g. Prostate Cancer, Lung Cancer
- SIP content copied from clinicaltrials.gov and pasted into OnCore
  - Objective
  - Description
  - Treatment
  - Eligibility
- Updates / missing data managed through weekly exception reports

Historical SIP Content Delivery:
— Cancer Center Website (2009)

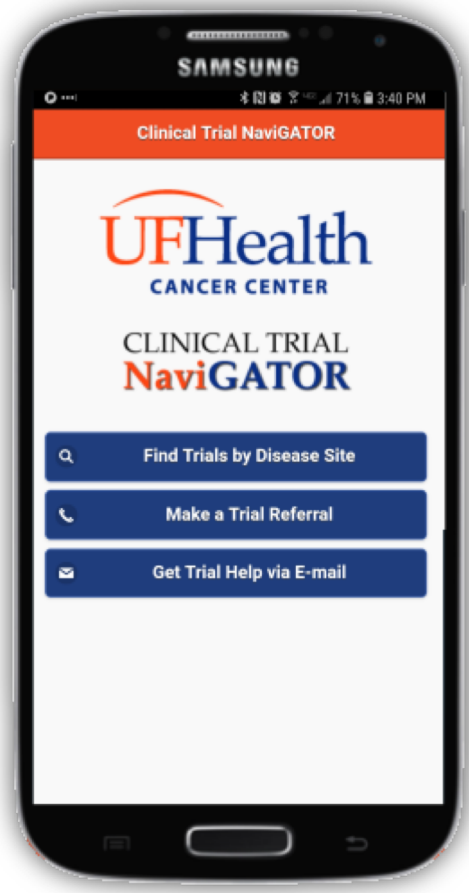
- Content audience:
  - Potential study participants (Public)
- Disease categories:
  - Web Descriptions used instead of default NCI disease sites
- Platform:
  - “Out of the box” Protocol Listing and Protocol Summary pages
  - Displayed on Cancer Center’s WordPress website using iframes

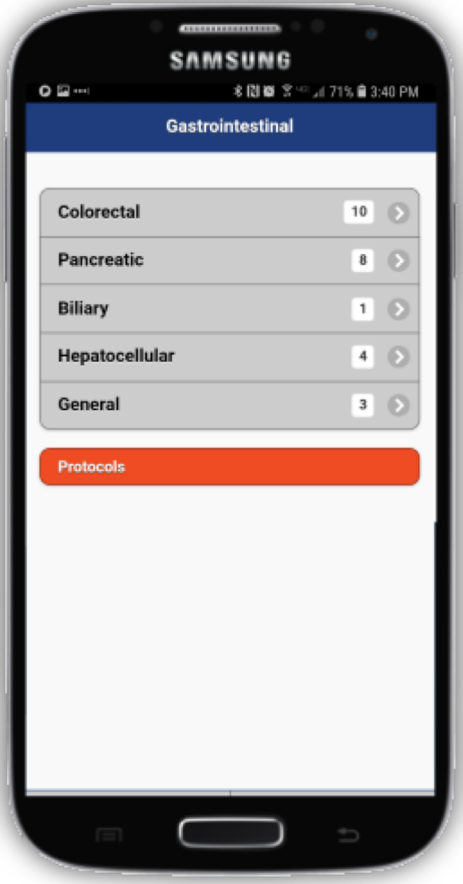


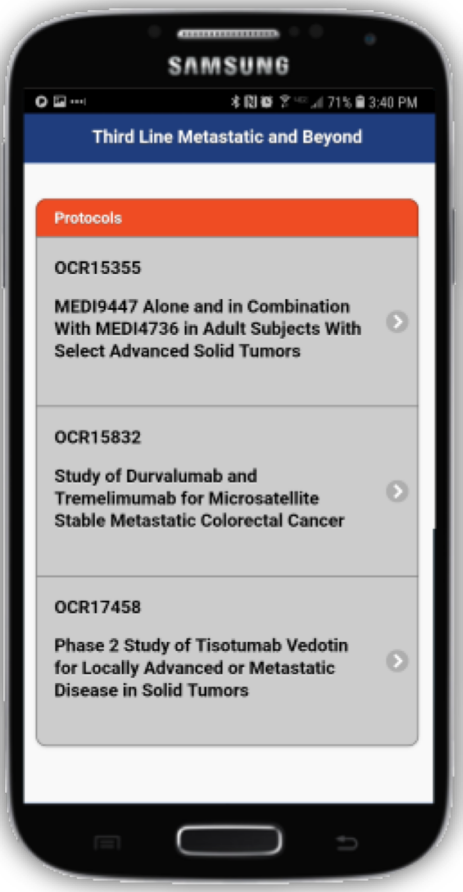
Protocol Listing

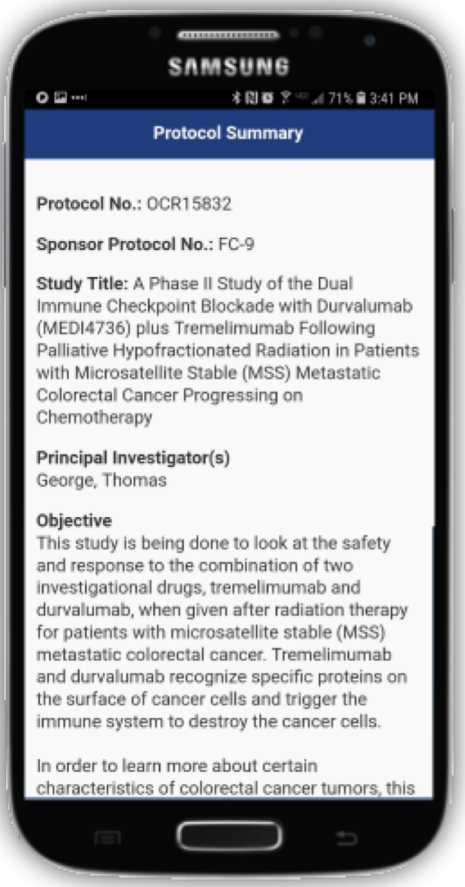


Protocol Summary


SAMSUNG
71% 3:40 PM
Clinical Trial NaviGATOR
UFHealth
CANCER CENTER
CLINICAL TRIAL
NaviGATOR
Find Trials by Disease Site
Make a Trial Referral
Get Trial Help via E-mail


SAMSUNG
71% 3:40 PM
Gastrointestinal
Colorectal 10
Pancreatic 8
Biliary 1
Hepatocellular 4
General 3
Protocols


SAMSUNG
71% 3:40 PM
Third Line Metastatic and Beyond
Protocols
OCR15355
MEDI9447 Alone and in Combination With MEDI4736 in Adult Subjects With Select Advanced Solid Tumors
OCR15832
Study of Durvalumab and Tremelimumab for Microsatellite Stable Metastatic Colorectal Cancer
OCR17458
Phase 2 Study of Tisotumab Vedotin for Locally Advanced or Metastatic Disease in Solid Tumors


SAMSUNG
71% 3:41 PM
Protocol Summary
Protocol No.: OCR15832
Sponsor Protocol No.: FC-9
Study Title: A Phase II Study of the Dual Immune Checkpoint Blockade with Durvalumab (MEDI4736) plus Tremelimumab Following Palliative Hypofractionated Radiation in Patients with Microsatellite Stable (MSS) Metastatic Colorectal Cancer Progressing on Chemotherapy
Principal Investigator(s)
George, Thomas
Objective
This study is being done to look at the safety and response to the combination of two investigational drugs, tremelimumab and durvalumab, when given after radiation therapy for patients with microsatellite stable (MSS) metastatic colorectal cancer. Tremelimumab and durvalumab recognize specific proteins on the surface of cancer cells and trigger the immune system to destroy the cancer cells.
In order to learn more about certain characteristics of colorectal cancer tumors, this

Establishing an Enterprise Approach to SIP

Goals:

1. Allow non-oncology departments to list their trials on department websites
2. Deploy quickly and easily
3. Improve upon current website aesthetics
4. Make website pages mobile-friendly
5. Minimize protocol setup and maintenance effort
6. Allow direct hyperlinking to protocol summary pages

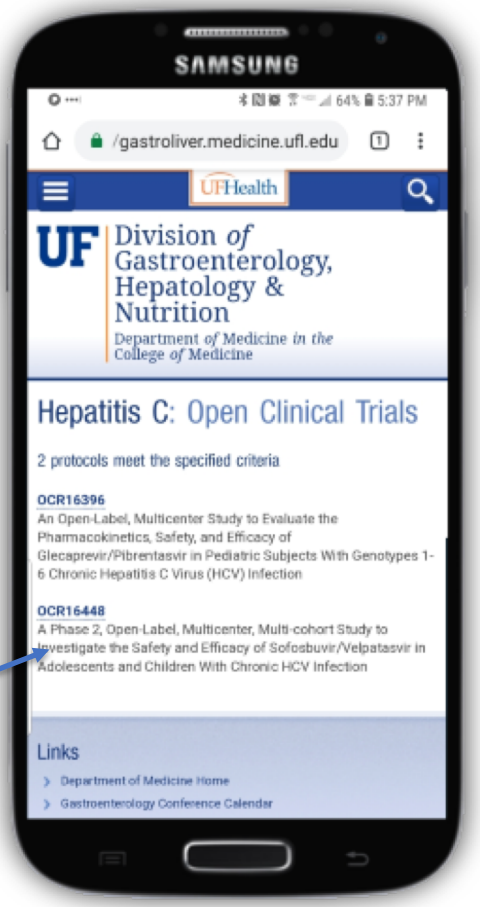
Enterprise SIP Content Management

- Central management of SIP Console records (OnCore team)
- Protocols linked to custom Web Descriptions in SIP
  - e.g. Hepatitis C, Parkinson Disease, Stroke
- Content imported using clinicaltrials.gov API**
  - Objective
  - Description
  - Treatment
  - Eligibility
- Updates and missing data managed through exception reports

*** SIP Console still used for overrides or studies not in clinicaltrials.gov*

SIP WordPress Plugin for Department Websites

- Content audience:
  - Potential study participants (Public)
- Disease categories:
  - Web Descriptions created after consultation with Study Teams
- Platform:
  - Protocol Listing and Protocol Summary pages using SIP WordPress Plugin
  - Displayed on Cancer Center's WordPress website
  - Displayed on Departmental WordPress websites
  - Full deployment in under 30 minutes



Protocol Listing

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Department of Medicine in the College of Medicine

Department of Medicine

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Home > Hepatology > Research > Clinical Trials > Protocol Summary

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    - PBC – Primary Biliary Cholangitis
  - Basic Research Labs
  - Our Most Recent Publications
  - Clinical and Translational Science Institute (CTSI)

Protocol Summary

Protocol No.: OCR16396

Sponsor Protocol No.: AbbVie M16-123

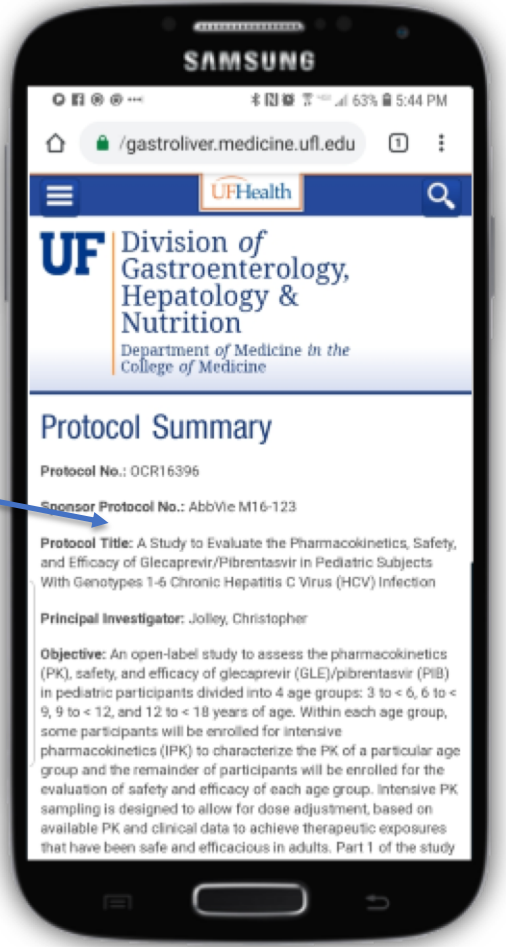
Protocol Title: A Study to Evaluate the Pharmacokinetics, Safety, and Efficacy of Glecaprevir/Pibrentasvir in Pediatric Subjects With Genotypes 1-6 Chronic Hepatitis C Virus (HCV) Infection

Principal Investigator: Jolley, Christopher

Objective: An open-label study to assess the pharmacokinetics (PK), safety, and efficacy of glecaprevir (GLE)/pibrentasvir (PIB) in pediatric participants divided into 4 age groups: 3 to < 6, 6 to < 9, 9 to < 12, and 12 to < 18 years of age. Within each age group, some participants will be enrolled for intensive pharmacokinetics (IPK) to characterize the PK of a particular age group and the remainder of participants will be enrolled for the evaluation of safety and efficacy of each age group. Intensive PK sampling is designed to allow for dose adjustment, based on available PK and clinical data to achieve therapeutic exposures that have been safe and efficacious in adults. Part 1 of the study will enroll participants into Cohort 1; Cohort 1 will include participants who are in 12 to < 18 years of age who can swallow the adult formulation of GLE/PIB. Part 2 of the study will enroll participants in the remaining age groups into Cohorts 2, 3, and 4; participants in these cohorts will receive the pediatric formulation of GLE/PIB. All participants will receive GLE/PIB for 8, 12, or 16 weeks depending on their hepatitis C virus (HCV) genotype, cirrhosis, and prior treatment experience status.

Phase: Phase III

Protocol Summary



Enterprise SIP Maintenance

- Weekly reports to identify upcoming or newly opened studies
  - Based on Protocol Status and SIP incomplete status
- Exception report for key data points
  - NCT ID (necessary for clinicaltrials.gov data feed)
  - Staff assigned with Study Site Contact role
  - Protocols have linked Web Description (and Flowchart node(s), if applicable)
- Other exceptions
  - Protocols that get Suspended, but are later re-opened, must be reactivated in the SIP Console

Enterprise SIP Considerations

- Overall SIP Strategy:
  - Hierarchal Flowchart structure vs. “flat” Web Description vs. custom approach
  - Maintenance – Centrally vs. Study Team managed
- What if departments do not “go live” with all of their Open to Accrual studies?
- IRB “approval”?
  - IRB approval is required when a clinical trial website goes beyond directory listings with basic descriptive information

    https://www.hhs.gov/ohrp/regulations-and-policy/guidance/clinical-trial-websites/index.html

SIP WordPress Plugin

Technical Implementation

Introducing OCR-SIP-Interface Plugin

- Seamlessly add protocol listings and protocol summaries to your Institutional WordPress sites via shortcodes

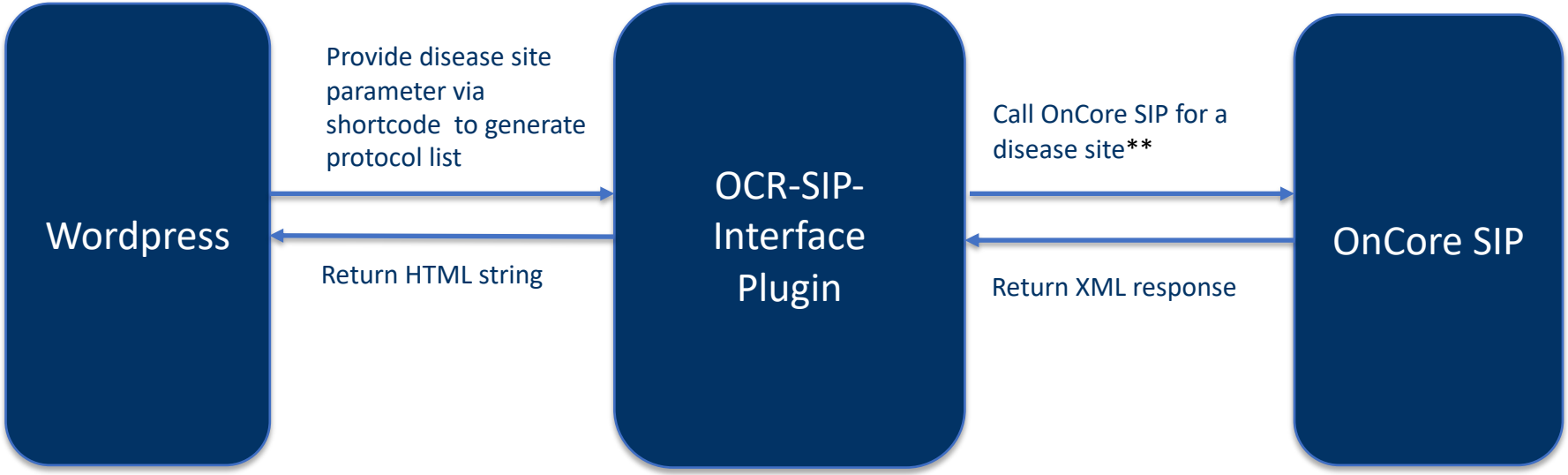
- How to use shortcodes?
  - Use **[protocol Summary]** shortcode to insert the protocol summary page
  - Use **[protocolsList disease_site_desc='diseaseSiteDesc']** shortcode to insert the protocol list page feed

SIP WordPress Plugin

Interface Architecture

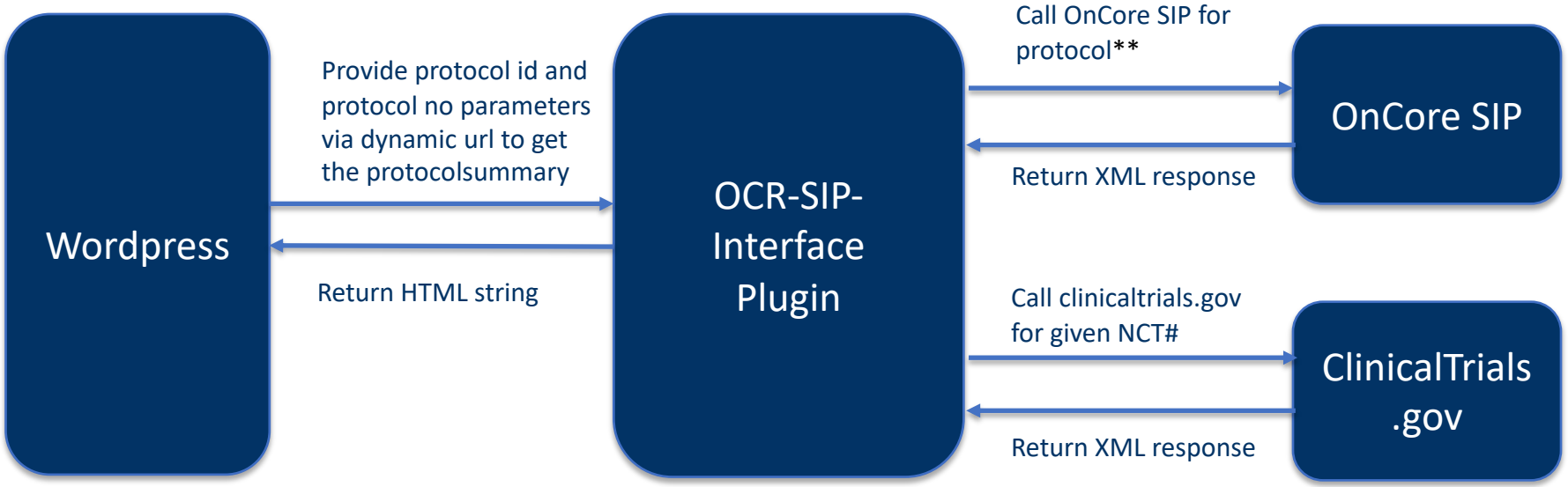
Protocol Listing

- *returns a list of protocols which belong to a specified web description*



Protocol Summary

returns descriptive details of a specified protocol



SIP WordPress Plugin

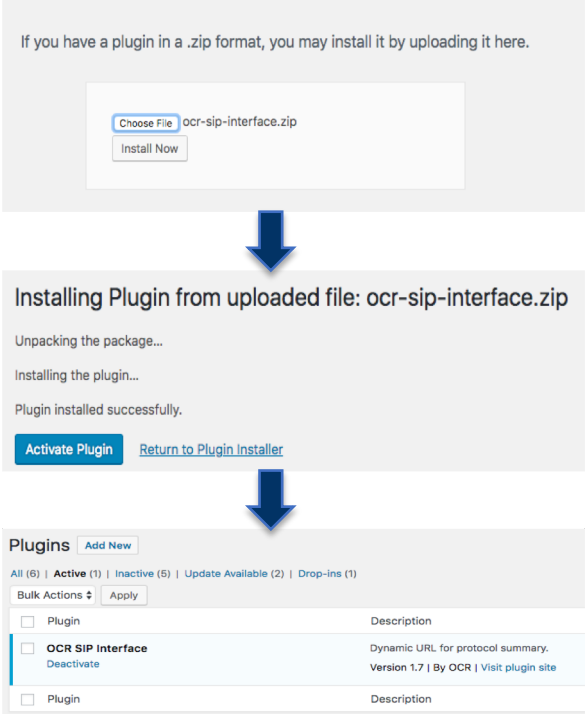
Website Setup

Enabling SIP Plugin on WordPress Site

- Step 1: Clone the public GitHub repository: https://github.com/UF-OCR/ocr-sip-interface into your machine
- Step 2: Update your SIP URL'S in ocr-sip-interface-config.php file

Enabling SIP Plugin on WordPress Site

- Step 3: Compress the ocr-sip-interface folder to zip format.
- Step 4: Upload the ocr-sip-interface.zip into wordpress site via plugin interface, and then activate it.



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Department of Medicine in the College of Medicine

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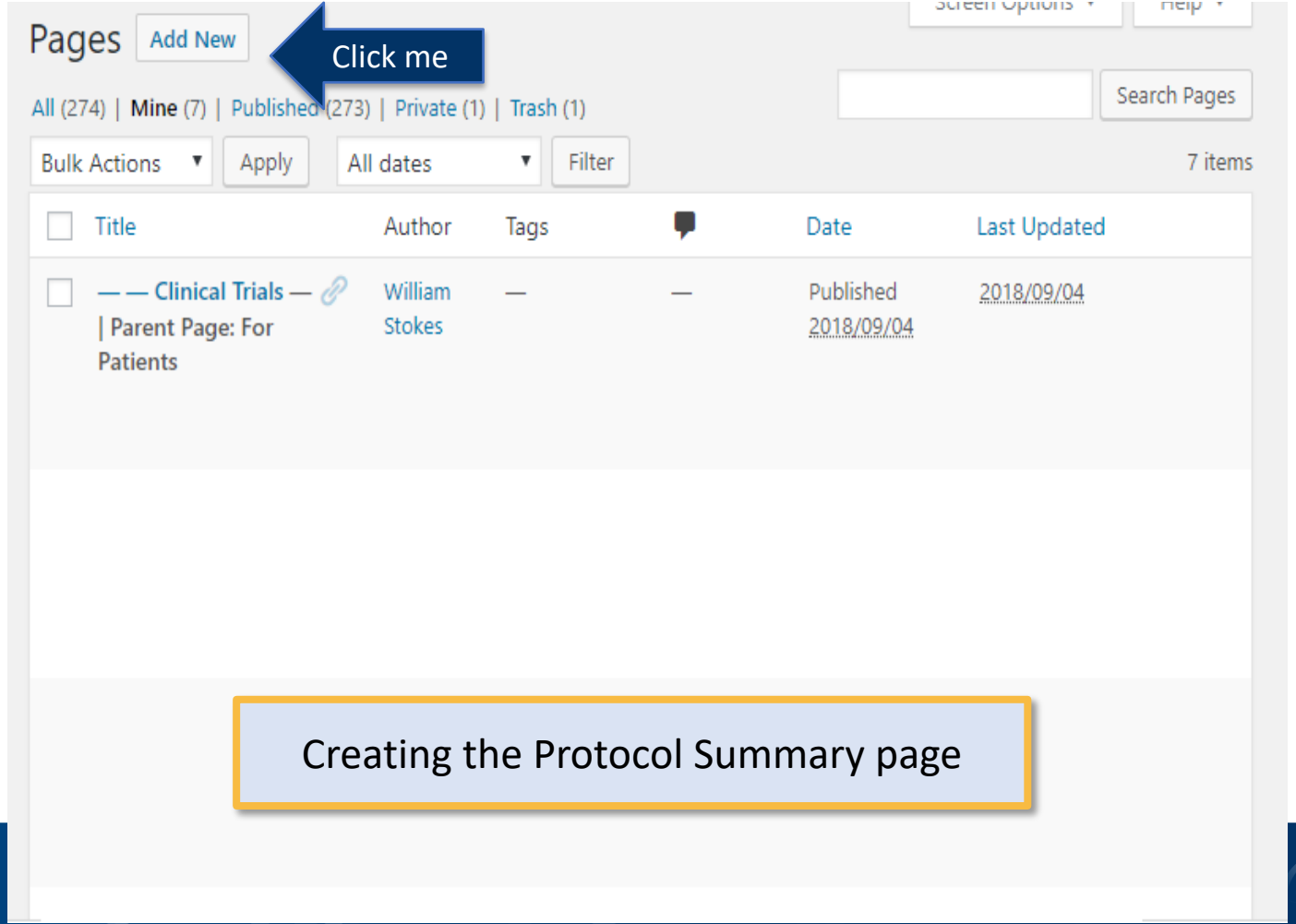
Clinical Trials

Clinical Trials

Select one of the following links to see our open clinical trials:

- Hepatitis C
- Cirrhosis
- Fatty Liver – NASH
- PBC – Primary Biliary Cholangitis

Click me


Pages
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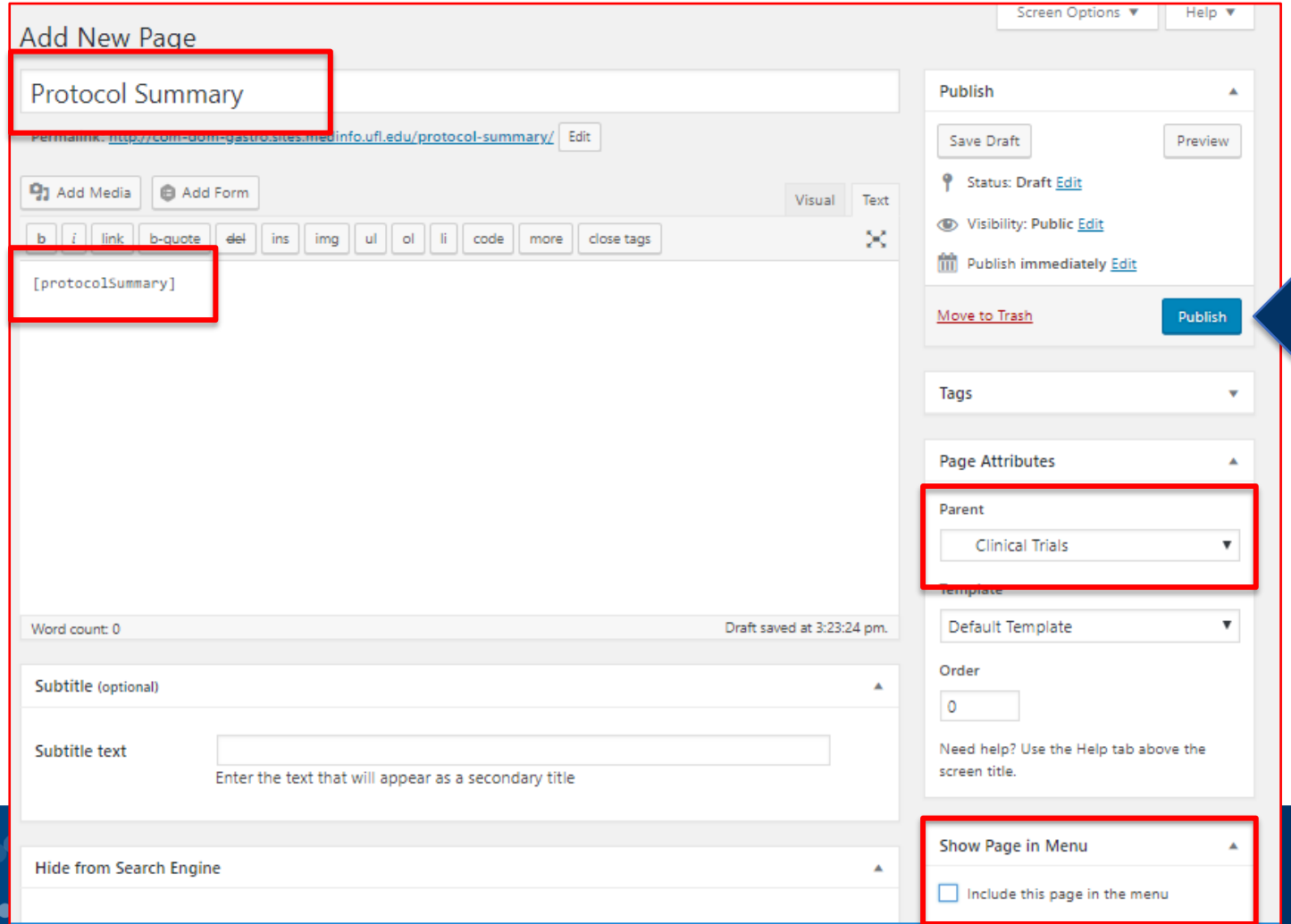
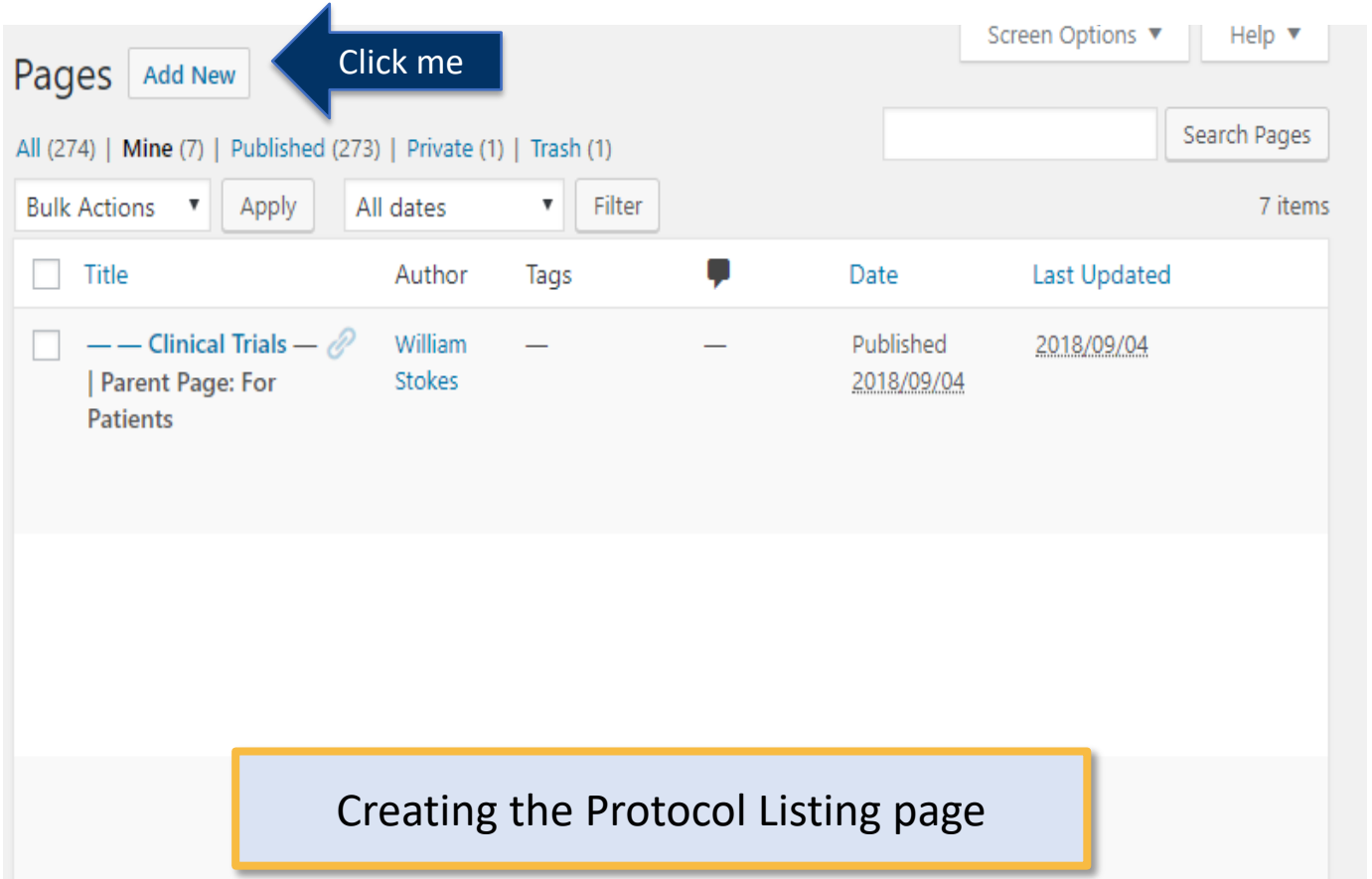
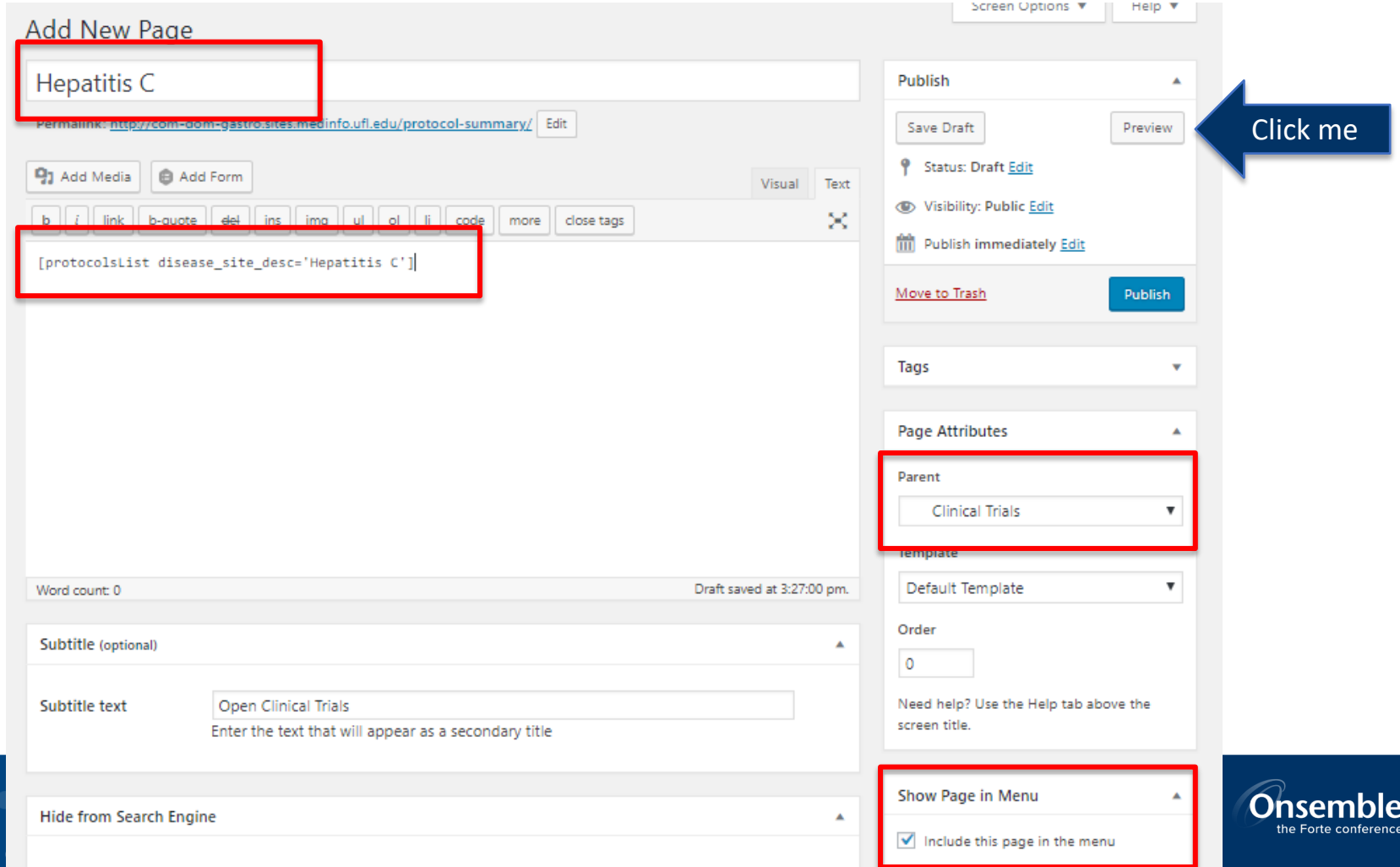
All (274) | Mine (7) | Published (273) | Private (1) | Trash (1)
Search Pages
Bulk Actions
Apply
All dates
Filter
7 items
Title
Author
Tags
Date
Last Updated
— — Clinical Trials — | Parent Page: For Patients
William Stokes
—
—
Published 2018/09/04
2018/09/04
Creating the Protocol Summary page



Click me



Creating the Protocol Listing page


Add New Page
Hepatitis C
Permalink: http://com-dom-gastro.sites.medinfo.ufl.edu/protocol-summary/ Edit
Add Media
Add Form
Visual
Text
b i link b-quote del ins img ul ol li code more close tags
[protocolsList disease_site_desc='Hepatitis C']
Word count: 0
Draft saved at 3:27:00 pm.
Subtitle (optional)
Subtitle text
Open Clinical Trials
Enter the text that will appear as a secondary title
Hide from Search Engine
Publish
Save Draft
Preview
Status: Draft Edit
Visibility: Public Edit
Publish immediately Edit
Move to Trash
Publish
Tags
Page Attributes
Parent
Clinical Trials
Default Template
Order
0
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  - Fatty Liver – NASH
  - PBC – Primary Biliary Cholangitis
- Basic Research Labs
- Our Most Recent Publications
- Clinical and Translational Science Institute (CTSI)

Liver Transplant

Hepatitis C: Open Clinical Trials

2 protocols meet the specified criteria

OCR16396
An Open-La…uate the Pharmacokinetics, Safety, and Efficacy of Glecaprevir/Pibrentasvir in Pediatric Subj…hronic Hepatitis C Virus (HCV) Infection

Click me

OCR16448
A Phase 2, Open-Label, Multicenter, Multi-cohort Study to Investigate the Safety and Efficacy of Sofosbuvir/Velpatasvir in Adolescents and Children With Chronic HCV Infection

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Phase: Phase III

Age Group: Children

Age: 3 Years - 17 Years

Gender: All

Scope: National

Treatment:

Experimental: Cohort 1: Adult formulation GLE/PIB subjects 12 to < 18yrs
Cohort 1: Adult formulation Glecaprevir (GLE)/Pibrentasvir (PIB) 300 mg/120 mg once daily (QD) for 8, 12, or 16 weeks depending on their hepatitis C virus (HCV) genotype, cirrhosis status, and prior treatment experience in participants 12 to < 18 years of age.

Screen Options ▼ Help ▼

Add New Page

Hepatitis C

Permalink: http://com-dom-gastro.sites.medinfo.ufl.edu/protocol-summary/ Edit

Add Media | Add Form | Visual | Text

b | i | link | b-quote | del | ins | img | ul | ol | li | code | more | close tags

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Word count: 0 Draft saved at 3:27:00 pm.

Subtitle (optional)

Subtitle text: Open Clinical Trials

Enter the text that will appear as a secondary title

Hide from Search Engine

Publish

Save Draft | Preview

Status: Draft Edit

Visibility: Public Edit

Publish immediately Edit

Move to Trash | Publish

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Tags

Page Attributes

Parent: Clinical Trials

Template: Default Template

Order: 0

Need help? Use the Help tab above the screen title.

Show Page in Menu

Include this page in the menu

Your department's clinical trial listing is now LIVE

Next Steps

Objective	Status
• Update Android and iOS apps using the clinicaltrials.gov API	Beta testing (release October 2018)
• Replace existing institutional clinical trials search tool	Planning phase
• Establish comprehensive clinical trials search / match application	Planning phase

Questions?

UF Office of Clinical Research development projects can be accessed from GitHub: https://github.com/UF-OCR