

The logo for Onsemble, featuring a stylized 'O' with a circular arrow around it, followed by the text 'Onsemble' and 'the Forte conference' below it.

Onsemble
the Forte conference

The logo for Forte, consisting of a stylized 'F' icon above the word 'FORTE' in all caps.

FORTE

A nighttime photograph of a city square, likely in Fort Worth, Texas. In the center, a large fountain with multiple jets of water is illuminated. In the background, the illuminated dome of the Texas State Capitol building is visible against a dark blue sky. The foreground shows the silhouettes of a crowd of people gathered around the fountain.

ONSEMBLE CONFERENCE

Powerful Ideas. Meaningful Connections.

Managing Enterprise Clinical Trial Listings with OnCore SIP

Joe Stokes

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University of Florida

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Application Developer, Office of Clinical Research
University of Florida

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
 - Study Description
 - Treatment details
 - 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

UFHealth Healing Learning Discovery Community visit University of Florida

UF Health Cancer Center
University of Florida Health

Locations Parking Make a Gift

Search Our Site

Contact Us: (352) 273-8010

Home Clinical Trials Current Clinical Trials **Bladder Cancer**

Current Clinical Trials

Bladder Cancer

- Brain and Nervous System
- Breast Cancer
- Colon Cancer
- Gastrointestinal Cancer
- Gynecologic Cancer
- Head & Neck Cancer
- Hematologic / Bone Marrow Diseases
- Leukemia
- Liver Cancer
- Lung Cancer
- Lymphoma – Hodgkin
- Lymphoma – Non–Hodgkin
- Myelodysplastic Syndrome (MDS)

Bladder Cancer

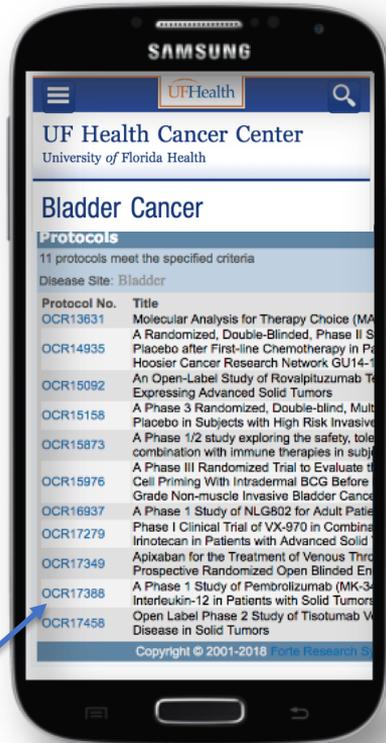
Protocols

11 protocols meet the specified criteria

Disease Site: Bladder

Protocol No.	Title
OCR13631	Molecular Analysis for Therapy Choice (MATCH)
OCR14935	A Randomized, Double-Blinded, Phase II Study of Maintenance Pembrolizumab versus Placebo after First-line Chemotherapy in Patients with Metastatic Urothelial Cancer: Hoosier Cancer Research Network GU14-182
OCR15092	An Open-Label Study of Rovelpituzumab Tesirine in Subjects with Delta-Like Protein 3-Expressing Advanced Solid Tumors
OCR15158	A Phase 3 Randomized, Double-blind, Multi-center Study of Adjuvant Nivolumab versus Placebo in Subjects with High Risk Invasive Urothelial Carcinoma
OCR15873	A Phase 1/2 study exploring the safety, tolerability, and efficacy of INCAGN01876 in combination with immune therapies in subjects with advanced or metastatic malignancies
OCR15976	A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming With Intradermal BCG Before Intravesical Therapy for BCG-Naive High-Grade Non-muscle Invasive Bladder Cancer
OCR16937	A Phase 1 Study of NLG802 for Adult Patients with Recurrent Advanced Solid Tumors
OCR17279	Phase I Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors
OCR17349	Apixaban for the Treatment of Venous Thromboembolism in Patients With Cancer: A Prospective Randomized Open Blinded End-Point (Probe) Study
OCR17388	A Phase 1 Study of Pembrolizumab (MK-3475) in Combination with Recombinant Interleukin-12 in Patients with Solid Tumors
OCR17458	Open Label Phase 2 Study of Tisotumab Vedotin for Locally Advanced or Metastatic Disease in Solid Tumors

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Protocol Listing

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Current Clinical Trials

- Bladder Cancer
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- Breast Cancer
- Colon Cancer
- Gastrointestinal Cancer
- Gynecologic Cancer
- Head & Neck Cancer
- Hematologic / Bone Marrow Diseases
- Leukemia
- Liver Cancer
- Lung Cancer
- Lymphoma – Hodgkin
- Lymphoma – Non-Hodgkin
- Myelodysplastic Syndrome (MDS)

Protocol No.: OCR13631

Sponsor Protocol No.: EAY131, MATCH

Study Title: Molecular Analysis for Therapy Choice (MATCH)

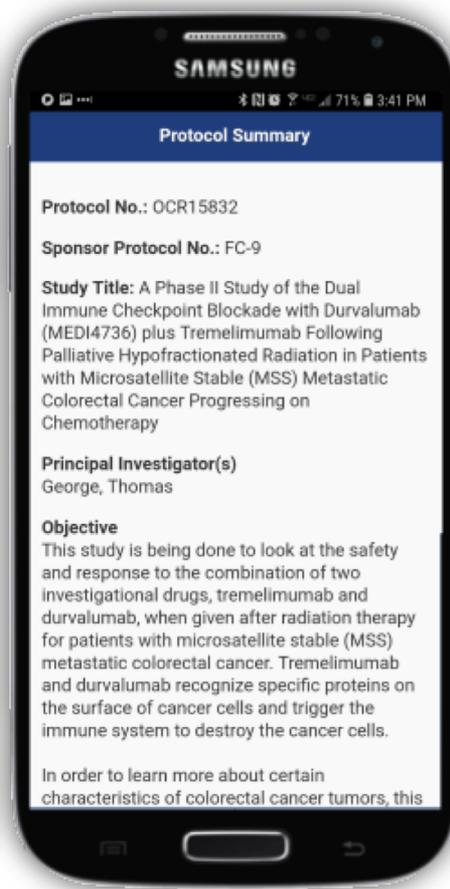
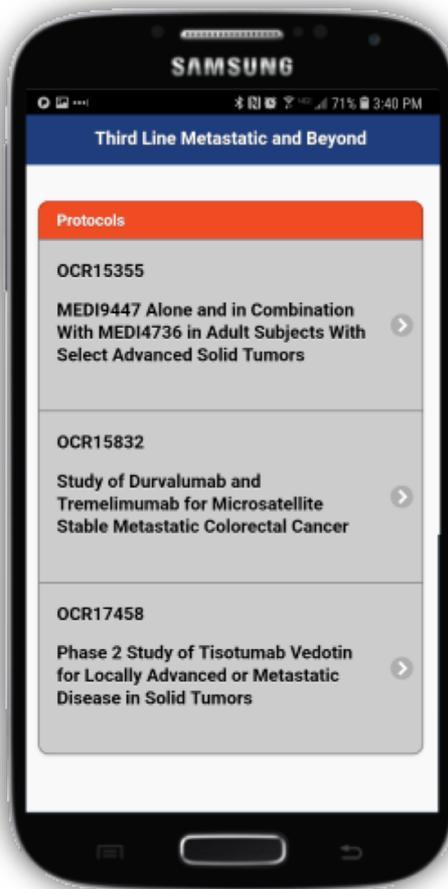
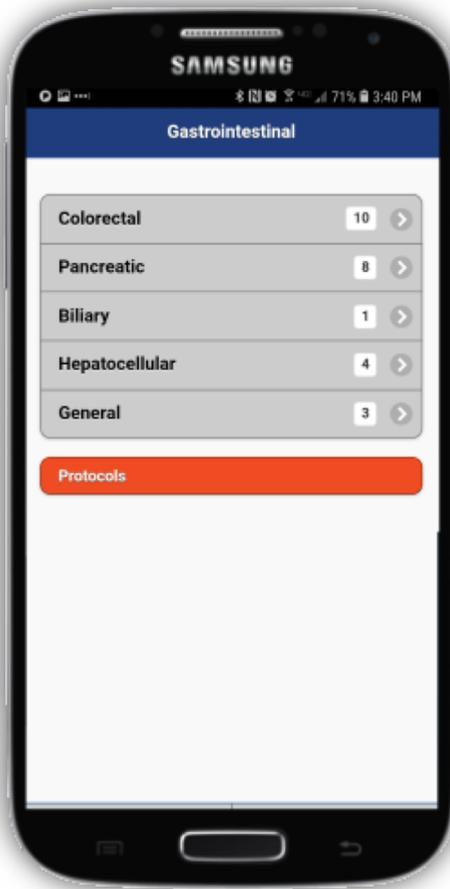
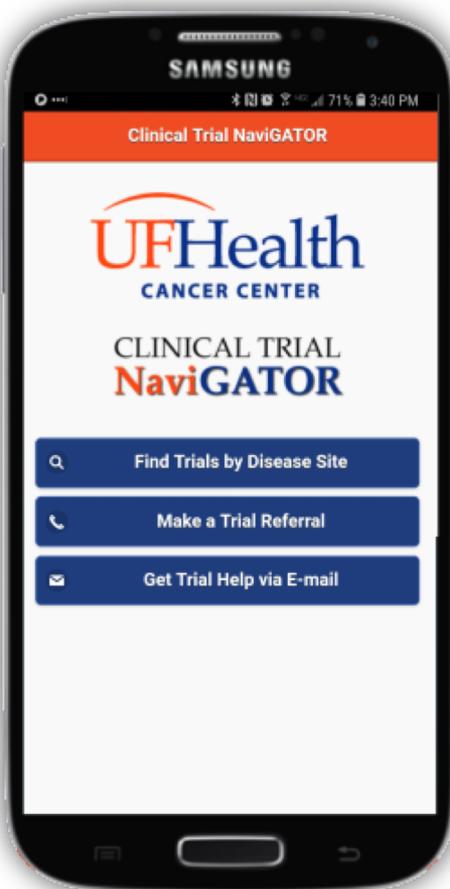
Principal Investigator(s)
George, Thomas

Objective
This phase II MATCH trial studies how well treatment that is directed by genetic testing works in patients with solid tumors or lymphomas that have progressed following at least one line of standard treatment or for which no agreed upon treatment approach exists. Genetic tests look at the unique genetic material (genes) of patients' tumor cells. Patients with genetic abnormalities (such as mutations, amplifications, or translocations) may benefit more from treatment which targets their tumor's particular genetic abnormality. Identifying these genetic abnormalities first may help doctors plan better treatment for patients with solid tumors, lymphomas, or multiple myeloma.

Description
(Screening): Patients undergo biopsy along with molecular characterization of the biopsy material for specific, pre-defined mutations, amplifications, or translocations of interest via tumor sequencing and immunohistochemistry. Consenting patients also undergo collection of blood samples for research purposes.
(Treatment): Patients are assigned to 1 of 24 treatment subprotocols based on molecularly-defined subgroup.
(Re-screening): Patients experiencing disease progression on the prior Step treatment or who could not

Protocol Summary





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

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For Physicians
For Patients
Research

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

Hepatitis C: Open Clinical Trials

2 protocols meet the specified criteria

OCR16396
An Open-Label, Multicenter Study to Evaluate the Pharmacokinetics, Safety, and Efficacy of Glecaprevir/Pibrentasvir in Pediatric Subjects With Genotypes 1-6 Chronic Hepatitis C Virus (HCV) Infection

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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Hepatitis C: Open Clinical Trials

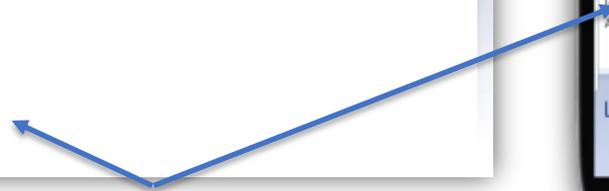
2 protocols meet the specified criteria

OCR16396
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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

Links

- Department of Medicine Home
- Gastroenterology Conference Calendar



Protocol Listing

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 - Basic Research Labs
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Protocol Summary

Protocol No.: OCR16396

Sponsor Protocol No.: AbbVie M16-123

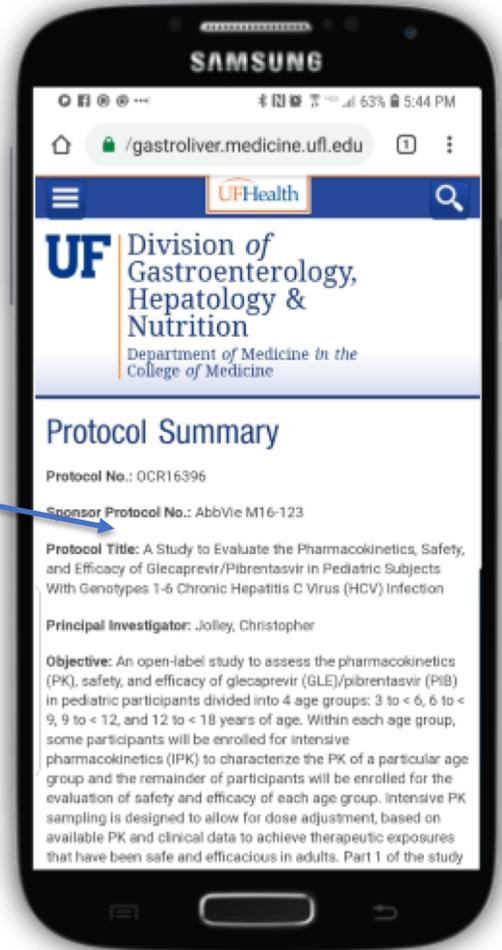
Protocol Title: A Study to Evaluate the Pharmacokinetics, Safety, and Efficacy of Glecaprevir/Pibrentasvir in Pediatric Subjects With Genotypes 1-6 Chronic Hepatitis C Virus (HCV) Infection

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



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Protocol Summary

Protocol No.: OCR16396

Sponsor Protocol No.: AbbVie M16-123

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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:
 - Hierarchical 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

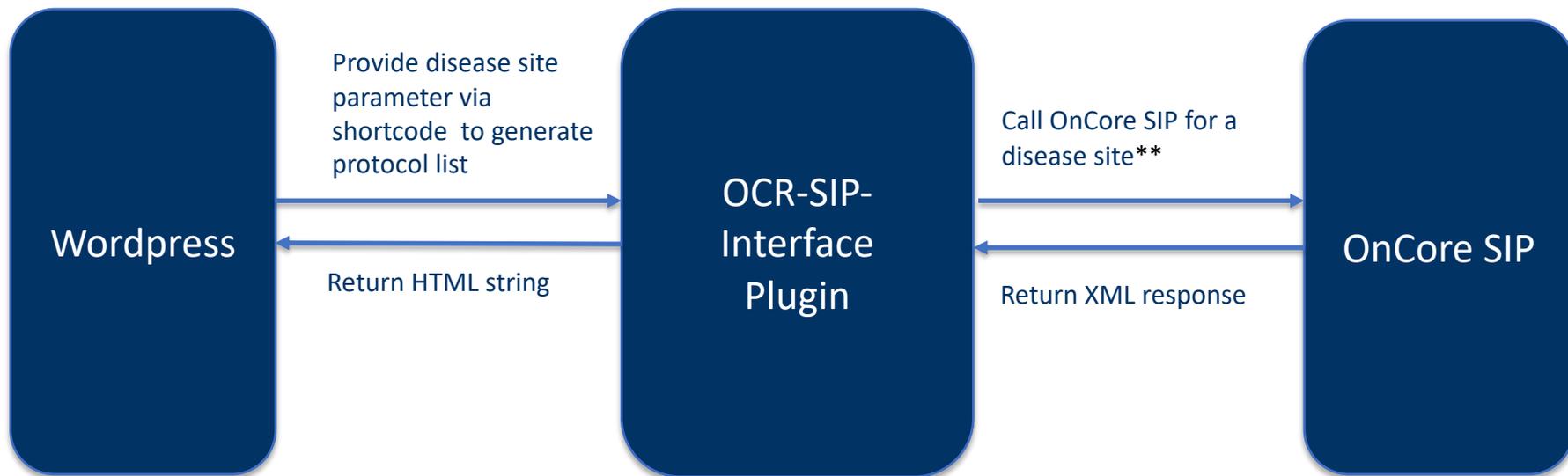
SIP WordPress Plugin



Interface Architecture

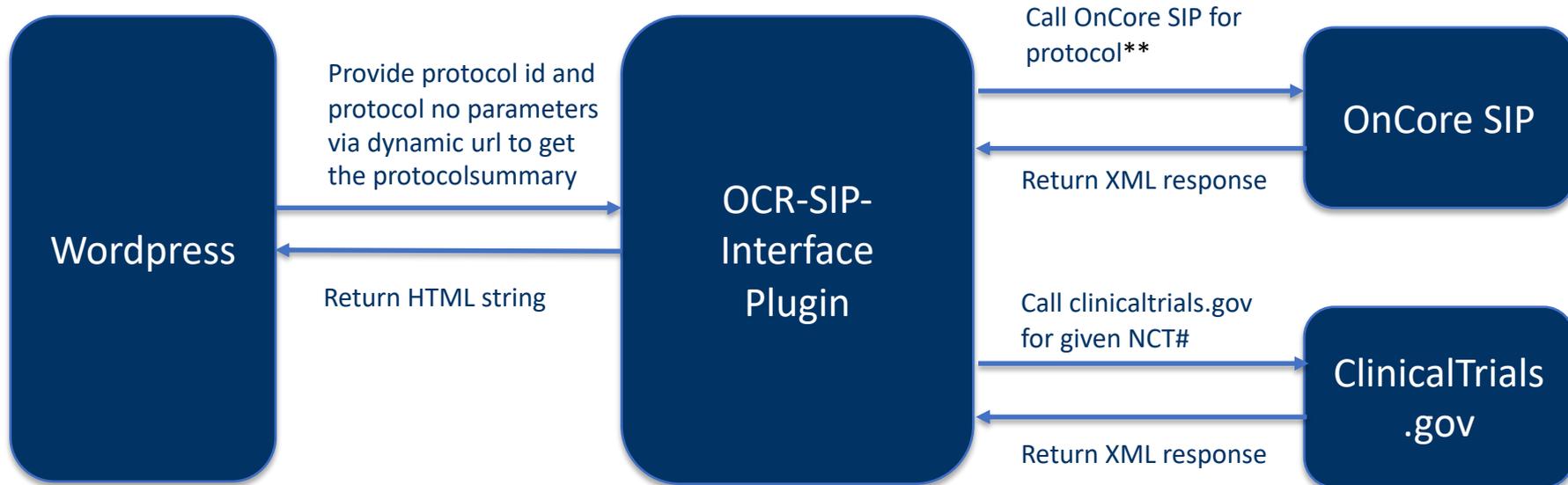
Protocol Listing

— 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

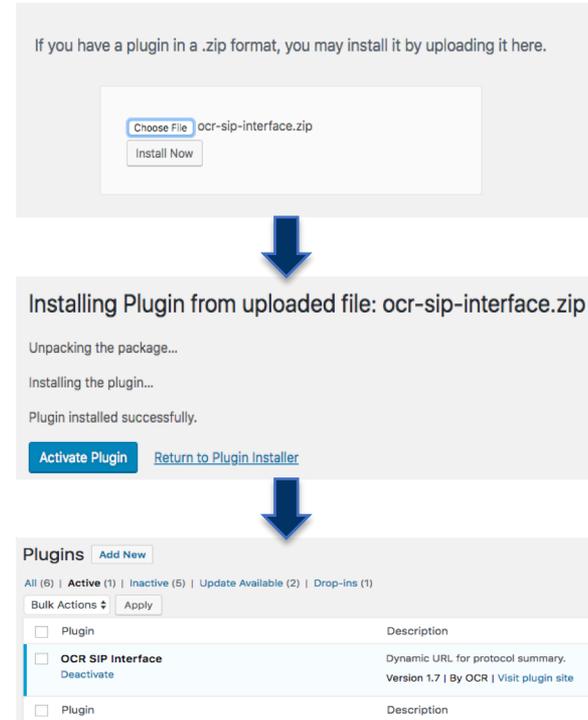
Enabling SIP Plugin on WordPress Site

- 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.



The image shows a three-step process for installing a plugin on WordPress:

- Step 1:** A screenshot of the WordPress plugin upload interface. It shows a text input field containing "ocr-sip-interface.zip" and a "Choose File" button. Below it is an "Install Now" button. The text above reads: "If you have a plugin in a .zip format, you may install it by uploading it here."
- Step 2:** A screenshot showing the installation progress. It says "Installing Plugin from uploaded file: ocr-sip-interface.zip". Below this, it shows "Unpacking the package...", "Installing the plugin...", and "Plugin installed successfully.". There are two buttons: "Activate Plugin" and "Return to Plugin Installer".
- Step 3:** A screenshot of the WordPress "Plugins" management page. It shows a table of installed plugins. The "OCR SIP Interface" plugin is highlighted in blue. The table has columns for "Plugin" and "Description". The description for "OCR SIP Interface" is "Dynamic URL for protocol summary. Version 1.7 | By OCR | Visit plugin site".

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Clinical Trials

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

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- [Fatty Liver – NASH](#)
- [PBC – Primary Biliary Cholangitis](#)



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Together we care for our patients and our communities.
Together we create unstoppable momentum.*



The Foundation for The Gator Nation



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All (274) | Mine (7) | Published (273) | Private (1) | Trash (1)

Search Pages

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7 items

<input type="checkbox"/>	Title	Author	Tags		Date	Last Updated
<input type="checkbox"/>	— — Clinical Trials —  Parent Page: For Patients	William Stokes	—	—	Published 2018/09/04	2018/09/04

Creating the Protocol Summary page

Add New Page

Protocol Summary

Permalink: <https://com-doin-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

[protocolSummary]

Word count: 0

Draft saved at 3:23:24 pm.

Subtitle (optional)

Subtitle text

Enter the text that will appear as a secondary title

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Publish

Save Draft

Preview

 Status: Draft [Edit](#)

 Visibility: Public [Edit](#)

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7 items

<input type="checkbox"/>	Title	Author	Tags		Date	Last Updated
<input type="checkbox"/>	Clinical Trials —  Parent Page: For Patients	William Stokes	—	—	Published 2018/09/04	2018/09/04

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](#)

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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

Screen Options

Help

Publish

Save Draft

Preview

Status: Draft [Edit](#)

Visibility: Public [Edit](#)

[Publish immediately](#) [Edit](#)

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Hepatitis C: Open Clinical Trials

2 protocols meet the specified criteria

OCR16396

An Open-Label, Randomized, Controlled Study to Evaluate the Pharmacokinetics, Safety, and Efficacy of Glecaprevir/Pibrentasvir in Pediatric Subjects With Chronic Hepatitis C Virus (HCV) Infection

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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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

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.

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

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Subtitle text

Open Clinical Trials

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—

**Your department's clinical trial
listing is now LIVE**

Next Steps

Objective	Status
<ul style="list-style-type: none">Update Android and iOS apps using the clinicaltrials.gov API	Beta testing (release October 2018)
<ul style="list-style-type: none">Replace existing institutional clinical trials search tool	Planning phase
<ul style="list-style-type: none">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>