

A blue-tinted photograph of a city at night. In the background, a large, ornate building with a dome (likely a state capitol) is illuminated. In the foreground, a large crowd of people is gathered, and a fountain with multiple jets of water is lit up. The overall scene is festive and urban.

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# Managing Enterprise Clinical Trial Listings with OnCore SIP

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## **Joe Stokes**

Associate Director, Office of Clinical Research  
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](https://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

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# UF Health Cancer Center

University of Florida Health

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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

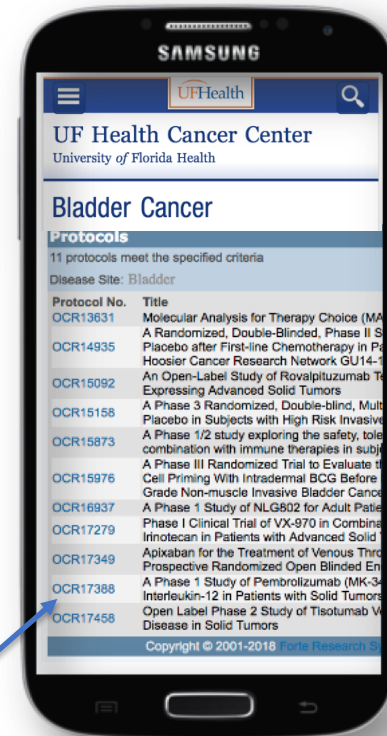
### Protocols

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

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)

**Protocol No.:** OCR13631

**Sponsor Protocol No.:** EAY131, MATCH

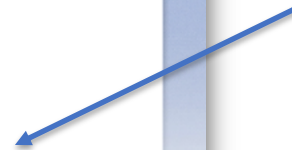
**Study Title:** Molecular Analysis for Therapy Choice (MATCH)

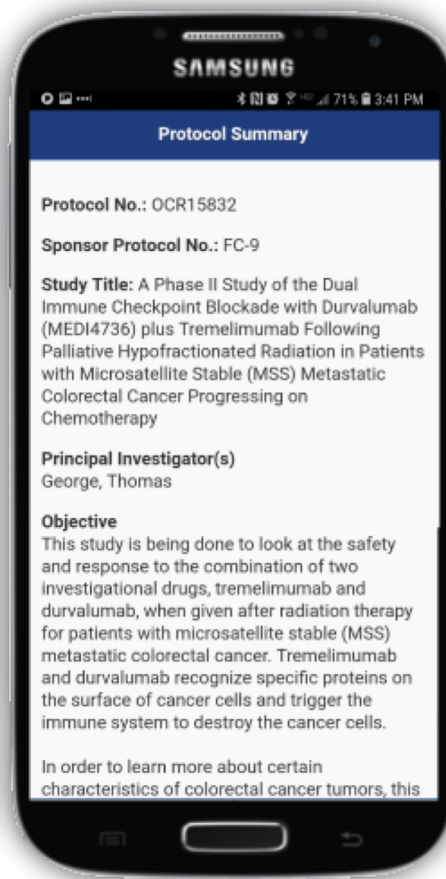
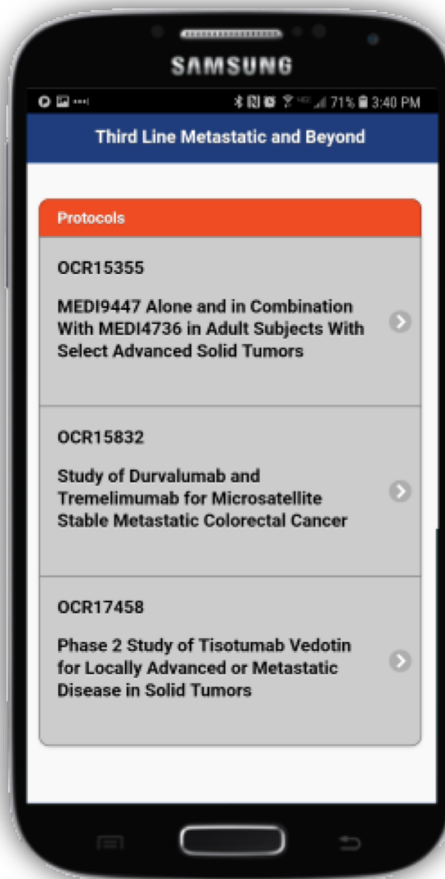
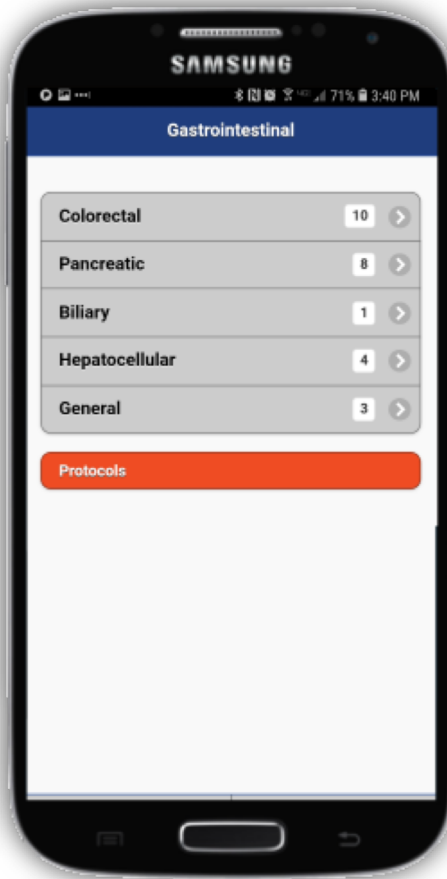
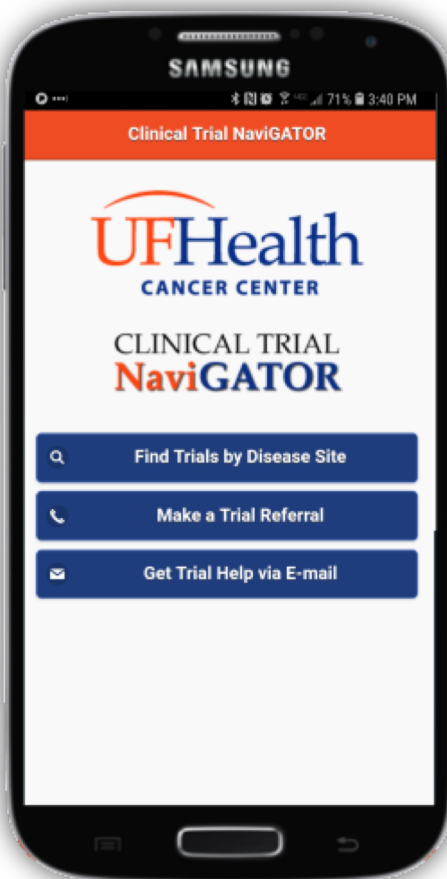
**Principal Investigator(s)**  
George, Thomas

**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](https://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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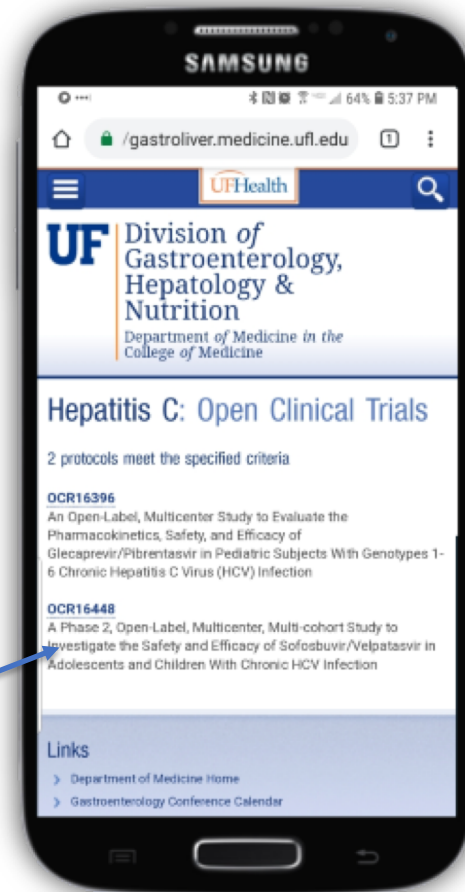
- Cirrhosis
- Fatty Liver – NASH
- PBC – Primary Biliary Cholangitis

## 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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PBC – Primary Biliary Cholangitis

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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

FORTE

Onsemble  
the Forte conference

# 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



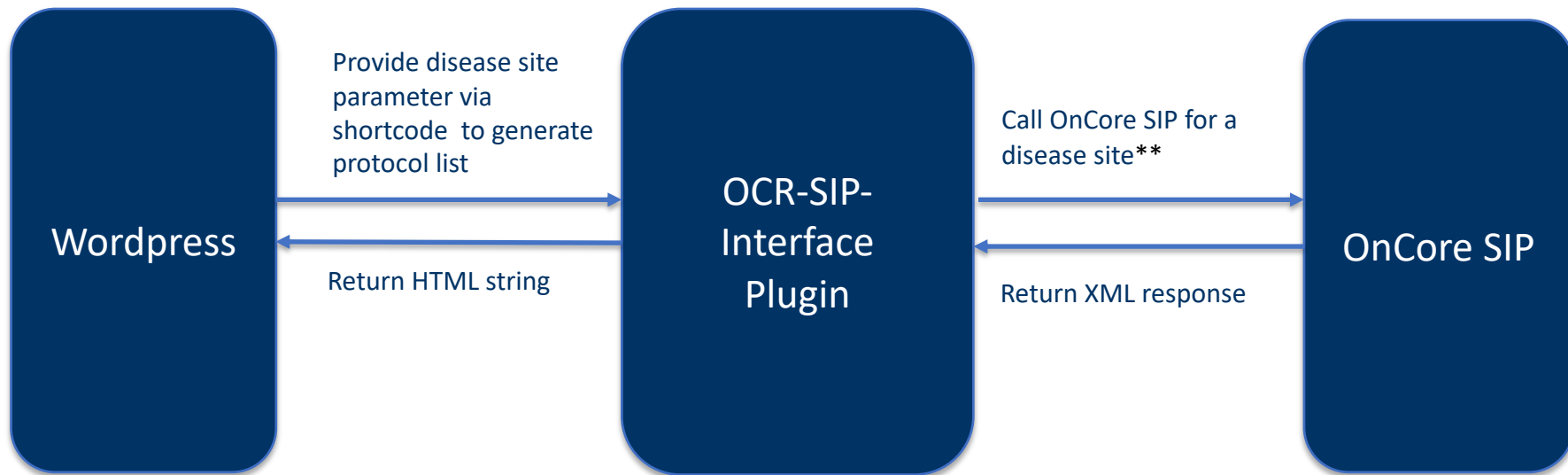
# SIP WordPress Plugin



## Interface Architecture

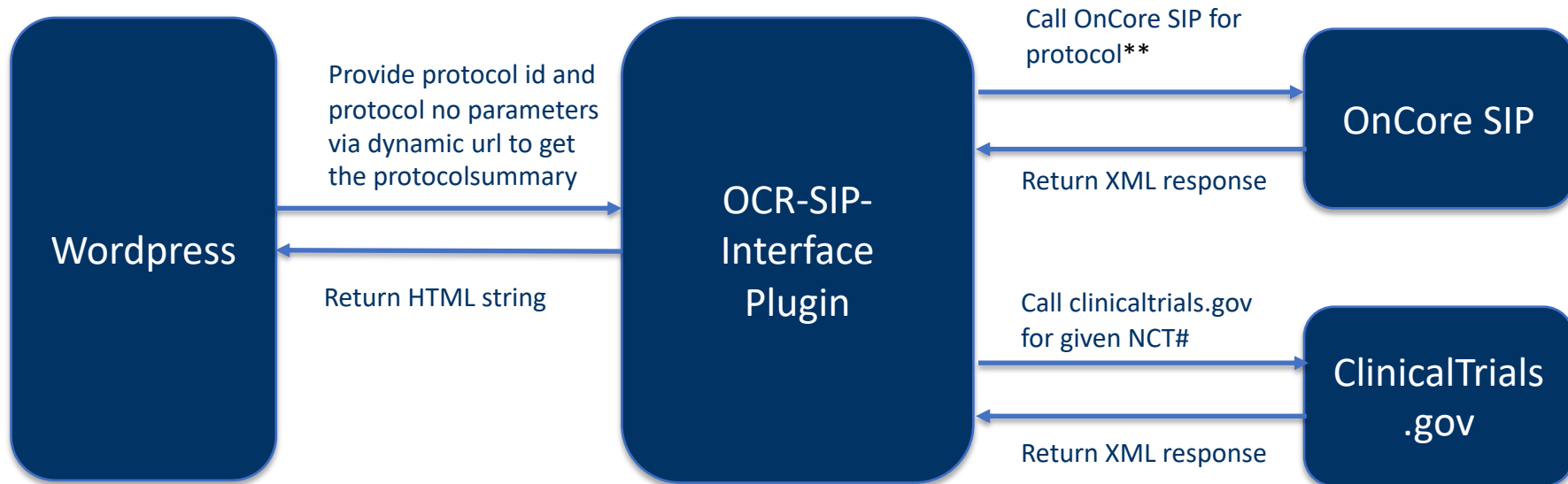
# Protocol Listing

— *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.

If you have a plugin in a .zip format, you may install it by uploading it here.

ocr-sip-interface.zip

↓

Installing Plugin from uploaded file: ocr-sip-interface.zip

Unpacking the package...

Installing the plugin...

Plugin installed successfully.

[Return to Plugin Installer](#)

↓

Plugins [Add New](#)

All (6) | **Active (1)** | Inactive (5) | Update Available (2) | Drop-ins (1)

Bulk Actions [Apply](#)

<input type="checkbox"/>	Plugin	Description
<input type="checkbox"/>	<b>OCR SIP Interface</b> <a href="#">Deactivate</a>	Dynamic URL for protocol summary. Version 1.7   By OCR   <a href="#">Visit plugin site</a>
<input type="checkbox"/>	Plugin	Description

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

- [Hepatitis C](#)
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- [PBC – Primary Biliary Cholangitis](#)



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
<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-dm-gastro.sites.medinfo.ufl.edu/protocol-summary/> [Edit](#)

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[protocolSummary]

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


Creating the Protocol Listing page

## Add New Page

Hepatitis C

Permalink: <http://com-dom-gastro.sites.medinfo.ufl.edu/protocol-summary/> [Edit](#)

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Word count: 0

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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

**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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## 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.

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Hepatitis C

Permalink: <http://com-dom-gastro.sites.medinfo.ufl.edu/protocol-summary/> [Edit](#)

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**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.

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**Your department's clinical trial  
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# Next Steps



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

# Questions?



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