



CTIS | A HEALTH
INFORMATICS
COMPANY

Proven Solutions. Improved Results.

Hepatitis C Database & Electronic Data Capture

Features

STUDY & USER MGMT

- Set up study, visits, schedule of events, & versioned CRFs
- Set up users, roles & access
- Track visits & CRF status
- Multi-site data collection
- Shared library

PARTICIPANTS

- Register and enroll participants
- Participant scheduling
- Track eligibility, informed consents
- Capture demographics, social history

STUDY DATA CAPTURE

- Intuitive & offline data entry & navigation in mobile tablet
- Scalable & customizable design to accommodate future needs
- Automatic soft & hard validations
- Upload & share documents

SPECIMEN

- Capture & store collected specimen information
- Label and track specimens

ANALYTICS

- Built-in longitudinal health study analytics & visualizations
- Easily export data & visuals to excel, document or images
- Exports to external applications for reporting and analysis

USER SUPPORT

- Online help, FAQ & training videos for self-directed eLearning
- Local language help text & audio to assist during data entry
- System manuals and deployment manuals for maintenance

SECURITY

- Encryption for data at rest (offline) and in-transit
- Audit trails and logging
- Deidentified reports
- Authentication and role based access control

DATABASE

- Synchronize offline data back to central database
- Data standards mapped fields
- Allows data QC & error correction
- Interface with external data sources
- Open source RDBMS

HOSTING

- Cloud hosted for web application
- Download and install mobile app from links in web application

Feature Map

Features	Web Application	Mobile Application
Study & User Setup	✓	✗
Participants	✓ [Register and enroll]	✓ [Questionnaires]
Study Data Capture	✗	✓
Specimen Tracking	✓ [tracking]	✓ [capture, label & tracking]
Reports & Analytics	✓	✓ [basic reports]
User Support	✓	✓
Offline Access	✗	✓
Security	✓	✓
Hosting & Database	✓	✓

Screen and Enroll New Patient

eCRFs (List Patients to select one)

LOGO

Find Patient

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical Sciences, Imphal ▾

Find Patient

Filter Patients

Sort by last edited ▾

Add New

HC005-007 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT

S

1

2

3

4

HC005-004 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT

S

1

2

3

4

HC005-003 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT

S

1

2

3

4

HC005-006 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT

S

1

2

3

4

HC005-001 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-01

EVENT

S

1

2

3

4

HC005-008 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-05

EVENT

S

1

2

3

4

HC005-002 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-01

EVENT

S

1

2

3

4

HC005-005 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT

S

1

2

3



4

New Patient - Screening Visit

LOGO

Screen Patient

Search App

 Anita Mehta ▾

eCRFs Summary Issue Resolution **New Patient**

Study: HEPC0123 Version 1.0 Site: Regional Institute of Medical... Patient: TBD [change](#) Encounter: TBD [change](#)

Find Patient >> New Patient

Encounter Date *

01-Dec-2017

Encounter Type *

Screening Visit ▾

If encounter type "Unscheduled", Specify reason for visit

First Name *

Middle Initial

Last Name *

Current Gender *

☐ Male ☐ Female

DOB *

MRN

Patient Consent Date

01-Dec-2017

Consent Version

1.0 ▾


Register Patient


Screening Visit - Eligibility

LOGO


Eligibility Questionnaire


Search App








Anita Mehta ▾











eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: TEMP-009, male [change](#)

Encounter: Screening Visit (01-Dec-2017) [change](#)

Find Patient >> New Patient



☒ Encounter Inform...

☐ Eligibility

☐ Orders

☐ Test Results

☐ Enrollment

Have you been tested for HCV Ab?

☐ Prior test ☐ Test at screening

If yes, provide the test date and result

☐ Positive ☐ Negative

Do you currently inject drugs?

☐ Yes ☐ No

Have you ever injected drugs?

☐ Yes ☐ No

Do you have HIV?

☐ Yes ☐ No

Register Patient

Screening Visit - Orders

LOGO

Orders

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: TEMP-009, male [change](#)

Encounter: Screening Visit (01-Dec-2017) [change](#)

Find Patient >> New Patient

Encounter Inform...

Eligibility

Orders

Test Results

Enrollment

Pick test to order

No earlier than

Add Order

T

HCV Antibody test with Reflex...

ORDER DT: 2017-12-01 NO EARLIER THAN: 2017-12-01

Screening Visit – Enroll Patient

LOGO

Enroll Patient

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: TEMP-009, male [change](#)

Encounter: Screening Visit (01-Dec-2017) [change](#)

Find Patient >> New Patient

☒ Encounter Inform...

☒ Eligibility

☒ Orders

☐ Test Results

☐ Enrollment

ELIGIBILITY PENDING MISSING INFORMATION, PROVIDE INFO TO PROCEED

Additional Information required:
1 - HCV Antibody test with Reflex to RNA test [Print order form](#)

Exit Enrollment & Complete Later

eCRFs (Enrollment pending patient added to list)

LOGO

Find Patient

Search App

Anita Mehta

▼

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical Sciences, Imphal

Find Patient >> New Patient >> Find Patient

Filter Patients

Sort by last edited

Add New

TEMP-009 ♂

DOB: 1970-01-10

ENROLLMENT: PENDING

EVENT

S

1

2

3

4

HC005-007 ♀

DOB: 1982-03-04

ENROLLMENT: 2017-11-10

EVENT

S

1

2

3

4

HC005-004 ♂

DOB: 1982-03-04

ENROLLMENT: 2017-11-10

EVENT

S

1

2

3

4

HC005-003 ♂

DOB: 1982-03-04

ENROLLMENT: 2017-11-10

EVENT

S

1

2

3

4

HC005-006 ♂

DOB: 1982-03-04

ENROLLMENT: 2017-11-10

EVENT

S

1

2

3

4

HC005-001 ♀

DOB: 1982-03-04

ENROLLMENT: 2017-11-01

EVENT

S

1

2

3

4

HC005-008 ♂

DOB: 1982-03-04

ENROLLMENT: 2017-11-05

EVENT

S

1

2

3

4

HC005-002 ♂

DOB: 1982-03-04

ENROLLMENT: 2017-11-01

EVENT

S

1

2

3

4

HC005-005 ♀

DOB: 1982-03-04

ENROLLMENT: 2017-11-10

EVENT

S

1

2

3

4

Screening Visit – Enroll Patient

LOGO

Enroll Patient

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: TEMP-009, male [change](#)

Encounter: Screening Visit (01-Dec-2017) [change](#)

Find Patient >> New Patient

☒ Encounter Inform...

☒ Eligibility

☒ Orders

☒ Test Results

☐ Enrollment

PATIENT IS ELIGIBLE FOR ENROLLMENT, PROCEED TO ENROLL

Enrollment Date

Enroll Patient

eCRFs (List Patients to select one)

LOGO

Find Patient

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical Sciences, Imphal ▾

Find Patient >> New Patient >> Find Patient

Filter Patients

Sort by last edited ▾

Add New

HC005-009 ♂

DOB 1970-01-10 ENROLLMENT 2017-12-10

EVENT +

S 1 2 3 4

HC005-007 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-004 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-003 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-006 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-001 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-01

EVENT +

S 1 2 3 4

HC005-008 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-05

EVENT +

S 1 2 3 4

HC005-002 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-01

EVENT +

S 1 2 3 4

HC005-005 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

Initial Visit

Initial Visit - List Patients to select one

LOGO

Find Patient

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical Sciences, Imphal ▾

Find Patient >> New Patient >> Find Patient

Filter Patients

Sort by last edited ▾

Add New

HC005-009 ♂

DOB 1970-01-10 ENROLLMENT 2017-12-10

EVENT +

S 1 2 3 4

HC005-007 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-004 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-003 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-006 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-001 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-01

EVENT +

S 1 2 3 4

HC005-008 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-05

EVENT +

S 1 2 3 4

HC005-002 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-01

EVENT +

S 1 2 3 4

HC005-005 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +



S 1 2 3 4

Initial Visit – Identify Encounter

LOGO

Encounter Information

Search App

  Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: TBD [change](#)

Find Patient >> Encounter Information

Encounter Date

20-Dec-2017

Encounter Type

Initial Visit ▾

If encounter type "Unscheduled", Specify reason for visit

Temperature

Systolic Blood Pressure

Diastolic Blood Pressure

Current weight

Current height

Patient Consent Date

01-Dec-2017

Consent Version

1.0 ▾

Reconsent



View Consent History

Initial Visit - Demographics

LOGO

Demographics






Search App


  Anita Mehta ▾


eCRFs Summary Issue Resolution New Patient


Study: HEPC0123 Version 1.0 Site: Regional Institute of Medical... Patient: HC005-009, male [change](#) Encounter: Initial Visit (20-Dec-2017) [change](#)


Find Patient >> Encounter Information >> Demographics


    











Encounter Inform...

Patient Profile

Demographics

Disease Characte...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Batch ID?

DOB?

Current Gender?

Gender at Birth?

Race?

Ethnicity?

Patient cohort status?

Status date?

Region/Town?

Country of birth?

State of residency?

Primary Insurance?



Secondary Insurance?

Initial Visit – Demographics (contd...-I)

LOGO

Demographics






Search App






 Anita Mehta ▾

eCRFs Summary Issue Resolution New Patient

Study: HEPC0123 Version 1.0 Site: Regional Institute of Medical... Patient: HC005-009, male [change](#) Encounter: Initial Visit (20-Dec-2017) [change](#)

Find Patient >> Encounter Information >> Demographics





Encounter Inform...

Patient Profile

Demographics

Disease Characte...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Primary Insurance?

Secondary Insurance?

Baseline height?

Date of baseline height?

Baseline weight?

Date of baseline weight?




Complete Demographics

Initial Visit - Disease Characteristics





LOGO

Disease Characteristics

Search App



Anita Mehta ▾



eCRFs

Summary

Issue Resolution

New Patient





Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

Find Patient >> Encounter Information >> Demographics >> Disease Characteristics



Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Date (Year) of diagnosis?

Genotype, if known?

☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Hep A Status?

☐ Immune ☐ Non-immune ☐ Vaccinated ☐ Unknown ☐ 4 ☐ 5 ☐ 6

Hep B Status?

☐ Immune ☐ Non-immune ☐ Co-Infection ☐ On HBV Meds ☐ Unknown ☐ No response to vaccine

HIV?

☐ Positive ☐ Positive on ARV ☐ Negative ☐ Unknown

If HIV negative, Date of last test?

Prior liver studies completed?

☐ None ☐ Liver biopsy ☐ Liver US ☐ CT Abdomen ☐ MRI Abdomen ☐ Fibrosure ☐ Fibroscan ☐ Endoscopy ☐ Colonoscopy ☐ Other

Grade?


☐ G1 ☐ G2 ☐ G3 ☐ G4

Stage?

☐ S1 ☐ S2 ☐ S3 ☐ S4

© Copyright 2018 CTIS

CTIS Confidential & Proprietary 18


 **CTIS** A HEALTH
INFORMATICS
COMPANY
Proven Solutions. Improved Results.


Initial Visit - Disease Characteristics (contd...-I)

LOGO

Disease Characteristics

Search App

 Anita Mehta ▾



eCRFs

Summary

Issue Resolution

New Patient



Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

Find Patient >> Encounter Information >> Demographics >> Disease Characteristics



Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Grade?

☐ G1 ☐ G2 ☐ G3 ☐ G4

Stage?

☐ S1 ☐ S2 ☐ S3 ☐ S4

Date of liver biopsy?

If Fibrosure?

☐ F0 ☐ F0-1 ☐ F1 ☐ F1-2 ☐ F2 ☐ F2-3 ☐ F3 ☐ F3-4 ☐ F4

If Fibroscan?

☐ F1 ☐ F2 ☐ F3 ☐ F4

If endoscopy?

☐ No varices ☐ Varices

Date of endoscopy?

If colonoscopy?

☐ Normal ☐ Abnormal


Date of colonoscopy?

Prior treatment?

☐ None ☐ IFN only ☐ IFN + RBV ☐ IFN + RBV + DAA
☐ Study medication ☐ Oral DAA ☐ Unknown ☐ Other

© Copyright 2018 CTIS

CTIS Confidential & Proprietary 19



 **CTIS** A HEALTH
INFORMATICS
COMPANY
Proven Solutions. Improved Results.

Initial Visit - Disease Characteristics (contd...-2)

LOGO

Disease Characteristics






Search App






Anita Mehta ▾

eCRFsSummaryIssue ResolutionNew Patient

Study: HEPC0123 Version 1.0Site: Regional Institute of Medical...Patient: HC005-009, male [change](#)Encounter: Initial Visit (20-Dec-2017) [change](#)

Find Patient >> Encounter Information >> Demographics >> Disease Characteristics





Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Prior treatment?

☐ None

☐ IFN only

☐ IFN + RBV

☐ IFN + RBV + DAA

☐ Study medication

☐ Oral DAA

☐ Unknown

☐ Other

Treatment outcome?

☐ Responder (SVR)

☐ Relapse

☐ Did not complete treatment

Current Assessment?

☐ No cirrhosis

☐ Cirrhosis compensated

☐ Cirrhosis decompensated

☐ Hepatocellular Carcinoma

☐ Child-Pugh Class A

☐ Child-Pugh Class B

☐ Child-Pugh Class C

☐ MELD score

☐ APRI score

☐ FIB-4 score

☐ Liver transplant

☐ Other

Immunization?

☐ Hep A

☐ Hep B

☐ Hep A + B

Complete Disease Characteristics

Initial Visit – Social factors

LOGO

Social factors

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

>> [Encounter Information](#) >> [Demographics](#) >> [Disease Characteristics](#) >> Social factors

Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Housing status?

☐ Own☐ Rent☐ Homeless☐ Other

Employment status?

☐ Steady income☐ Daily wage☐ Unemployed☐ Other

Marital Status?

Education Level?

Incarceration history?



Complete Social factors






Initial Visit – Lab Results

LOGO

Lab Results

Search App

 Anita Mehta ▾



Encounter Inform...

Patient Profile

- Demographics
- Disease Charact...
- Social factors
- Risk factors
- Hep C History
- Co-morbidities
- Medication history
- Procedure history
- Review of systems
- Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

>> [Procedure history](#) >> [Review of Systems](#) >> [Clinical Impression](#) >> Lab Results



Tests	01-Dec-2017 (Screening)	Normal Ranges
Endocrinology	xyz	xyz
Hematology	xyz	xyz
Hepatitis	xyz	xyz
HIV	xyz	xyz
Lipid Profile	xyz	xyz
Serologic		
AST (SGOT)	xyz	xyz
ALT (SGPT)	xyz	xyz
Alkaline Phosphatase	xyz	xyz
Biln.Totl	xyz	xyz
Bili Dir	xyz	xyz
Bili Ind	xyz	xyz
Albumin	xyz	xyz
Total Prot	xyz	xyz
GGT (SGGT)	xyz	xyz

Patient Current Meds

xyz

xyz

xyz

xyz

xyz

xyz


xyz

xyz

xyz

© Copyright 2018 CTIS

CTIS Confidential & Proprietary 22



 **CTIS** A HEALTH
INFORMATICS
COMPANY
Proven Solutions. Improved Results.






Initial Visit – Lab Results (contd...-I)

LOGO

Lab Results

Search App

 Anita Mehta ▾



Encounter Inform...

Patient Profile

- Demographics
- Disease Charact...
- Social factors
- Risk factors
- Hep C History
- Co-morbidities
- Medication history
- Procedure history
- Review of systems
- Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

>> [Procedure history](#) >> [Review of Systems](#) >> [Clinical Impression](#) >> Lab Results



Tests	01-Dec-2017 (Screening)	Normal Ranges
GGT (SGGT)	xyz	xyz
INR	xyz	xyz
Platelet	xyz	xyz
Viral Hepatitis		
HAV		
HepA Ab IgG	xyz	xyz
HepA Ab IgM	xyz	xyz
HepA total Ab	xyz	xyz
HBV		
Hep B Surf Ab	xyz	xyz
Hep B Surf Ag	xyz	xyz
HB Core Ab	xyz	xyz
HBcAB IgG	xyz	xyz
HBcAB IgM	xyz	xyz
HepBCoreAg	xyz	xyz

Patient Current Meds

xyz

xyz

xyz

xyz

xyz

xyz

xyz



xyz






Initial Visit – Lab Results (contd...-2)

LOGO

Lab Results

Search App

 Anita Mehta ▾



eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

>> [Procedure history](#) >> [Review of Systems](#) >> [Clinical Impression](#) >> Lab Results



Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Tests	01-Dec-2017 (Screening)	Normal Ranges
HepBCoreAg	xyz	xyz
HepBEAb	xyz	xyz
HepBEAg	xyz	xyz
HBV VL QUAL	xyz	xyz
HepB DNA	xyz	xyz
HCV		
HepC AB	xyz	xyz
HCV VL QUAL	xyz	xyz
HepC PCR	xyz	xyz
HDV		
Hep D AB	xyz	xyz
Genotype		
Genotype 1a	xyz	xyz
Genotype 1b	xyz	xyz
Genotype 2	xyz	xyz

Patient Current
Meds

xyz

xyz

xyz

xyz

xyz

xyz


xyz

xyz

xyz

© Copyright 2018 CTIS

CTIS Confidential & Proprietary 24



 **CTIS** A HEALTH
INFORMATICS
COMPANY
Proven Solutions. Improved Results.






Initial Visit – Lab Results (contd...-3)

LOGO

Lab Results

Search App

 Anita Mehta ▾



eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

>> [Procedure history](#) >> [Review of Systems](#) >> [Clinical Impression](#) >> Lab Results



Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Tests	01-Dec-2017 (Screening)	Normal Ranges
Genotype 2	xyz	xyz
Genotype 3	xyz	xyz
Genotype 4	xyz	xyz
Genotype 5	xyz	xyz
Genotype 6	xyz	xyz
Staging		
Biopsy	xyz	xyz
Fibrosure testing		
Fibrosis stage	xyz	xyz
Neuroinflammatory Activity	xyz	xyz
FIB4	xyz	xyz
MELD	xyz	xyz
APRI	xyz	xyz
Genetic Markers		
Interleukin 28B Polymorphism (IL-28B)	xyz	xyz

Patient Current Meds

xyz

xyz

xyz

xyz

xyz


xyz

xyz

xyz

© Copyright 2018 CTIS

CTIS Confidential & Proprietary 25



 **CTIS** A HEALTH
INFORMATICS
COMPANY
Proven Solutions. Improved Results.






Initial Visit – Lab Results (contd...-4)

LOGO

Lab Results

Search App

 Anita Mehta ▾



eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

>> [Procedure history](#) >> [Review of Systems](#) >> [Clinical Impression](#) >> Lab Results



Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Tests	01-Dec-2017 (Screening)	Normal Ranges
Interleukin 28B Polymorphism (IL-28B)	xyz	xyz
HCV resistance mutations		
NS3	xyz	xyz
NS5A	xyz	xyz

Patient Current Meds

xyz

xyz

xyz

xyz

xyz

xyz

xyz



xyz






Initial Visit – Orders & Referrals

LOGO

Orders and Referrals

Search App

 Anita Mehta ▾



eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

>> [Lab results](#) >> [Vitals](#) >> [Physical Exam](#) >> Orders & Referrals



Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Tests to order

No earlier than (Date)

Select tests ▾

Add new

Medications

Select medications ▾

Add new

Referrals

Select referrals ▾

Add new

Initial Visit – Discharge

LOGO

Discharge

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: Initial Visit (20-Dec-2017) [change](#)

>> [Vitals](#) >> [Physical Exam](#) >> [Orders](#) >> Discharge

Encounter Inform...

Patient Profile

Demographics

Disease Charact...

Social factors

Risk factors

Hep C History

Co-morbidities

Medication history

Procedure history

Review of systems

Clinical Impres...

Lab Results

Vitals

Physical Exam

Orders

Discharge

Education provided?

☐ Hep C natural history

☐ Hep C treatment

☐ Alcohol counselling

☐ Safe injection practice & harm rejection counselling

☐ Sexual transmission

☐ Contraception education

Discharge Instructions / notes?

Complete Discharge

Print order / referral forms

Second Visit

Second Visit - List Patients to select one

LOGO

Find Patient

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical Sciences, Imphal ▾

Find Patient

Filter Patients

Sort by last edited ▾

Add New

HC005-009 ♂

DOB 1970-01-10 ENROLLMENT 2018-03-10

EVENT +

S 1 2 3 4

HC005-007 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-004 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-003 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-006 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

HC005-001 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-01

EVENT +

S 1 2 3 4

HC005-008 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-05

EVENT +

S 1 2 3 4

HC005-002 ♂

DOB 1982-03-04 ENROLLMENT 2017-11-01

EVENT +

S 1 2 3 4

HC005-005 ♀

DOB 1982-03-04 ENROLLMENT 2017-11-10

EVENT +

S 1 2 3 4

Second Visit – Identify Encounter

Encounter Information

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#)

Encounter: TBD [change](#)

Find Patient >> Encounter Information

Encounter Date

20-Jan-2018

Encounter Type

Second Visit ▾

If encounter type "Unscheduled", Specify reason for visit

Temperature

Systolic Blood Pressure

Diastolic Blood Pressure

Current weight

Current height

Patient Consent Date

01-Dec-2017

Consent Version

1.0 ▾

Reconsent



View Consent History






Second Visit – Lab Results

LOGO

Lab Results

Search App

 Anita Mehta ▾



eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#) [profile](#)

Encounter: Second Visit (20-Jan-2018) [change](#)

Find Patient >> Encounter Information >> Lab Results



Encounter Inform...

Lab Results

Treatment Resp...

Vitals

Physical Exam

Orders

Discharge

Tests	20-Dec-2017 (Initial Visit)	01-Dec-2017 (Screening)	Normal Range
Endocrinology	xyz	xyz	xyz
Hematology	xyz	xyz	xyz
Hepatitis	xyz	xyz	xyz
HIV	xyz	xyz	xyz
Lipid Profile	xyz	xyz	xyz
Serologic			
AST (SGOT)	xyz	xyz	xyz
ALT (SGPT)	xyz	xyz	xyz
Alkaline Phosphatase	xyz	xyz	xyz
Biln.Totl	xyz	xyz	xyz
Bili Dir	xyz	xyz	xyz
Bili Ind	xyz	xyz	xyz
Albumin	xyz	xyz	xyz
Total Prot	xyz	xyz	xyz
GGT (SGGT)	xyz	xyz	xyz

Patient Current
Meds

xyz

xyz

xyz

xyz

xyz

xyz

xyz



xyz






Second Visit – Lab Results (contd...-I)

LOGO

Lab Results

Search App

 Anita Mehta ▾



Encounter Inform...

Lab Results

Treatment Resp...

Vitals

Physical Exam

Orders

Discharge

eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#) [profile](#)

Encounter: Second Visit (20-Jan-2018) [change](#)

Find Patient >> Encounter Information >> Lab Results



Tests	20-Dec-2017 (Initial Visit)	01-Dec-2017 (Screening)	Normal Range
GGT (SGGT)	xyz	xyz	xyz
INR	xyz	xyz	xyz
Platelet	xyz	xyz	xyz
Viral Hepatitis			
HAV			
HepA Ab IgG	xyz	xyz	xyz
HepA Ab IgM	xyz	xyz	xyz
HepA total Ab	xyz	xyz	xyz
HBV			
Hep B Surf Ab	xyz	xyz	xyz
Hep B Surf Ag	xyz	xyz	xyz
HB Core Ab	xyz	xyz	xyz
HBcAB IgG	xyz	xyz	xyz
HBcAB IgM	xyz	xyz	xyz
HepBCoreAg	xyz	xyz	xyz

Patient Current Meds

xyz

xyz

xyz

xyz

xyz

xyz

xyz



xyz






Second Visit – Lab Results (contd...-2)

LOGO

Lab Results

Search App

 Anita Mehta ▾



Encounter Inform...

Lab Results

Treatment Resp...

Vitals

Physical Exam

Orders

Discharge

eCRFs

Summary

Issue Resolution

New Patient






Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change profile](#)

Encounter: Second Visit (20-Jan-2018) [change](#)

Find Patient >> Encounter Information >> Lab Results



Tests	20-Dec-2017 (Initial Visit)	01-Dec-2017 (Screening)	Normal Range
HepBCoreAg	xyz	xyz	xyz
HepBEAb	xyz	xyz	xyz
HepBEAg	xyz	xyz	xyz
HBV VL QUAL	xyz	xyz	xyz
HepB DNA	xyz	xyz	xyz
HCV			
HepC AB	xyz	xyz	xyz
HCV VL QUAL	xyz	xyz	xyz
HepC PCR	xyz	xyz	xyz
HDV			
Hep D AB	xyz	xyz	xyz
Genotype			
Genotype 1a	xyz	xyz	xyz
Genotype 1b	xyz	xyz	xyz
Genotype 2	xyz	xyz	xyz

Patient Current Meds

xyz

xyz

xyz

xyz

xyz

xyz

xyz

xyz

Second Visit – Lab Results (contd...-3)

LOGO

Lab Results

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#) [profile](#)

Encounter: Second Visit (20-Jan-2018) [change](#)

Find Patient >> Encounter Information >> Lab Results

Encounter Inform...

Lab Results

Treatment Resp...

Vitals

Physical Exam

Orders

Discharge

Tests	20-Dec-2017 (Initial Visit)	01-Dec-2017 (Screening)	Normal Range
Genotype 2	xyz	xyz	xyz
Genotype 3	xyz	xyz	xyz
Genotype 4	xyz	xyz	xyz
Genotype 5	xyz	xyz	xyz
Genotype 6	xyz	xyz	xyz
Staging			
Biopsy	xyz	xyz	xyz
Fibrosure testing			
Fibrosis stage	xyz	xyz	xyz
Neuroinflammatory Activity	xyz	xyz	xyz
FIB4	xyz	xyz	xyz
MELD	xyz	xyz	xyz
APRI	xyz	xyz	xyz
Genetic Markers			
Interleukin 28B Polymorphism (IL-28B)	xyz	xyz	xyz

Patient Current
Meds

xyz

xyz

xyz

xyz

xyz

xyz

xyz

xyz

Second Visit – Lab Results (contd...-4)

LOGO

Lab Results

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#) [profile](#)

Encounter: Second Visit (20-Jan-2018) [change](#)

Find Patient >> Encounter Information >> Lab Results

☒ Encounter Inform...

☒ Lab Results

☐ Treatment Resp...

☐ Vitals

☐ Physical Exam

☐ Orders

☐ Discharge

Tests	20-Dec-2017 (Initial Visit)	01-Dec-2017 (Screening)	Normal Ranges
Interleukin 28B Polymorphism (IL-28B)	xyz	xyz	xyz
HCV resistance mutations			
NS3	xyz	xyz	xyz
NS5A	xyz	xyz	xyz

Patient Current Meds

xyz

xyz

xyz

xyz

xyz

xyz

xyz

xyz

Second Visit – Treatment Response

Treatment Response

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#) [profile](#)

Encounter: Second Visit (20-Jan-2018) [change](#)

Find Patient >> Encounter Information >> Lab Results >> Treatment Response

Encounter Inform...

Lab Results

Treatment Resp...

Vitals

Physical Exam

Orders

Discharge

Adherence?

☐ No missed doses in last 4 weeks

☐ 1-3 missed doses in last 4 weeks

☐ 3-10 missed doses in last 4 weeks

☐ >10 missed doses in last 4 weeks

HCV Current Treatment Response?

☐ No week 4 viral response

☐ Yes week 4 viral response

☐ SVR (Sustained viral response 12 yes)

☐ SVR (Sustained viral response 24 yes)

☐ Relapse

☐ Stopped treatment

☐ Lost to follow up

Clinical Adverse Events?

☐ Grade I

☐ Grade II

☐ Grade III

☐ Grade IV



Complete Treatment Response

Second Visit – Orders & Referrals

LOGO

Orders and Referrals






Search App

  Anita Mehta ▼

eCRFs Summary Issue Resolution New Patient

Study: HEPC0123 Version 1.0 Site: Regional Institute of Medical... Patient: HC005-009, male [change profile](#) Encounter: Second Visit (20-Jan-2018) [change](#)

>> [Lab results](#) >> [Vitals](#) >> [Physical Exam](#) >> Orders & Referrals

Encounter Inform...

Lab Results

Treatment Resp...

Vitals

Physical Exam

Orders

Discharge

Tests to order

No earlier than (Date)

Select tests ▼

Add new

Medications

Select medications ▼

Add new


Referrals

Select referrals ▼

Add new

© Copyright 2018 CTIS

CTIS Confidential & Proprietary 38

 **CTIS** A HEALTH
INFORMATICS
COMPANY
Proven Solutions. Improved Results.

Second Visit – Discharge

LOGO

Discharge

Search App

Anita Mehta ▾

eCRFs

Summary

Issue Resolution

New Patient

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical...

Patient: HC005-009, male [change](#) [profile](#)

Encounter: Second Visit (20-Jan-2018) [change](#)

>> [Vitals](#) >> [Physical Exam](#) >> [Orders](#) >> Discharge

■ Encounter Inform...

■ Lab Results

■ Treatment Resp...

■ Vitals

■ Physical Exam

■ Orders

■ Discharge

Education provided?

☐ Hep C natural history

☐ Hep C treatment

☐ Alcohol counselling

☐ Safe injection practice & harm rejection counselling

☐ Sexual transmission

☐ Contraception education

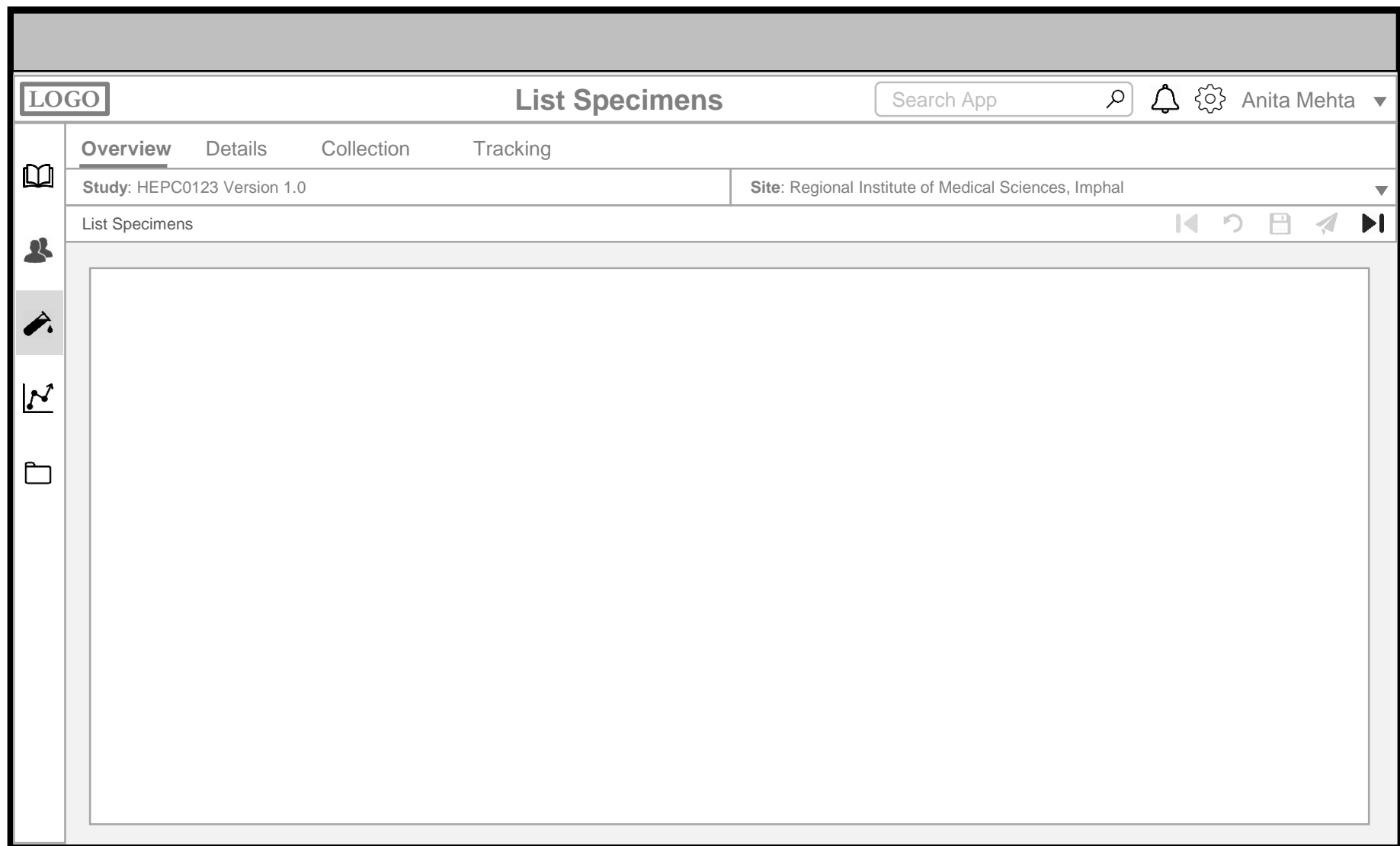
Discharge Instructions / notes?

Complete Discharge

Print order / referral forms

Specimen Tracking

Specimen Collection & Tracking (TBD)



Reports & Analytics

Reports & Analytics (TBD)

The screenshot displays a web application interface for "Enrollment Reports". At the top, there is a header bar with a "LOGO" placeholder, the title "Enrollment Reports", a "Search App" input field, and user controls including a notification bell, a settings gear, and the user name "Anita Mehta" with a dropdown arrow. Below the header, a navigation bar contains tabs for "Performance", "Quality", "Audit Trails", and "Data Exports", with "Performance" currently selected. The main content area is divided into a left sidebar and a central panel. The sidebar includes icons for a book, users, a pencil, a line graph, and a folder, corresponding to the menu items: "Study: HEPC0123 Version 1.0", "Reports", "Enrollment Rep...", "Accrual Reports", "Patient Profile", "Adverse Events", and "Other". The "Patient Profile" item is highlighted. The central panel shows a large empty box, likely for a report or chart, with navigation controls (back, forward, search, etc.) at the top right.

Document Library

Document Library (TBD)

LOGO

Document Library

Search App

Anita Mehta ▾

Find

Details

Issue Resolution

Study: HEPC0123 Version 1.0

Site: Regional Institute of Medical Sciences, Imphal ▾

Document Library

Protocol Summary Documents

[Study Team Update](#)

[Medical Officer Update](#)

Informed Consent

[Study Team Update](#)

Other

[Letter of Amendment](#)



THANK YOU

CTIS, Inc.

One Research Ct., Suite 200
Rockville, MD 20850

Tel: 301-948-3033

www.ctisinc.com