

## Feature Details

**ID 103****Project HealthCOM2-HABIT-II****Title HealthCOM for the HABIT-II Clinical Trial**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	
<b>Current Design:</b>	<b>Original US#:</b> 0	<b>Category:</b>
<b>In Phase 1?:</b> <input type="checkbox"/>	<b>Backlog Type:</b> <input type="checkbox"/>	<b>Category Type:</b> <input type="checkbox"/>

### Description

As a Company, we need a webspace on HealthCOM for the HABIT-II clinical trial to present data coming over a wireless internet connection from the HeartCheck device deployed to study subjects (patients) and the Simplified CRF deployed to the hospital staff and administered by Simplified, to various parties involved in the clinical trial.

- Minimum requirements for data presentation is a data summary page containing the following:1. Patient tracking summary page or dashboard for nurses to see summary data on all patients.2. Patient Specific page that presents study data in graphic and tabular forms for:
  - Subject medical history summary▪ BNP data from HeartCheck in graphic and tabular form including tests that erred out
- HF related death and hospitalization occurrences from the CRF
  - Weights data from HeartCheck in graphic and tabular form▪ Symptoms data from HeartCheck in graphic and tabular form▪ Dosage data from key heart failure medications from the CRF in graphic and tabular form▪ Key laboratory results from the CRF in tabular form▪ Secondary cardiovascular medications from the CRF in tabular form• User roles and access levels will be defined as follows:1. Alere Data Management Administrator: Has unrestricted access to all data in all study arms from all institutions. Can download data and create separate databases from the HealthCOM data.2. Alere Clinical Trial Manager/Clinical Research Associate: Has unrestricted access to view all data in all study arms from all institutions. Cannot download data or retrieve data.3. Physician/Staff: Has read-only access to data from their institution alone, restricted by study arm.4. Compliance Committee: Has read-only access to data from all institutions, restricted by study arm.5. Data and Safety Monitoring Committee: Has read-only access to all data from all institutions in all study arms.• Details to follow in additional "User Stories"

**ID 104****Project HealthCOM2-HABIT-II****Title Date ranges for Patient Reports**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	
<b>Current Design:</b>	<b>Original US#:</b> 0	<b>Category:</b>
<b>In Phase 1?:</b> <input type="checkbox"/>	<b>Backlog Type:</b> <input type="checkbox"/>	<b>Category Type:</b> <input type="checkbox"/>

### Description

As a user of the HABIT-II HealthCOM portal, I need to be able to conveniently set date ranges for the patient reports so that I am not bogged down in too much detail. § The default ranges should include: 3, 7, 14, 30, 60, 90, 120, 180 days and also include a Start-Stop date entry field.

**ID 105****Project HealthCOM2-HABIT-II****Title Site Caseload Status Report Page**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	
<b>Current Design:</b>	<b>Original US#:</b> 0	<b>Category:</b>

## Feature Details

In Phase 1?: ☐

Backlog Type: ☐

Category Type: ☐

### Description

As a Nurse using the HABIT-II HealthCOM portal, I need to be able to see color coded summaries of the status of all of patient's at my hospital in a way that I am not bogged down in too much detail. § Use the current HealthCOM summary page as a model but replace Status, Client, Glucose, BP, etc., with the following: Date Fields: Client (Subject ID) (Subject ID matched to meter ID using CRF data.) Date of last transaction (local time), BNP, Weight, answers to 5 symptom questions, Alerts summary (Y/N), Red, Orange, Yellow, Green color coding of information based on alerts generated. (HeathCOM data and Alerts algorithms data) § The data presented on this page must be linked to the permissions set for each arm of the study. Subjects in the BNP arm may have different data displayed than patients in the SOC arm.

**ID 106**

**Project HealthCOM2-HABIT-II**

**Title Y-Axis rescaling**

**Build #**

**Start Date**

**Priority**

**Original Work 0**

**Due Date**

**Status**

**Actual Work 0**

**Completion Date**

**Percent 0  
Complete**

**Requested By**

**Assigned To**

**Current Design:**

**Original US#: 0**

**Category:**

**In Phase 1?: ☐**

**Backlog Type: ☐**

**Category Type: ☐**

### Description

As a Nurse using the HABIT-II HealthCOM portal, I may need to be able to adjust the Y-axis of the BNP and Weights graphics to be able to properly interpret some data and trends in the data, especially in instances where there is a large difference in scale in some data compared to other data.

**ID 107**

**Project HealthCOM2-HABIT-II**

**Title Subject Report Demographics and Medical History**

**Build #**

**Start Date**

**Priority**

**Original Work 0**

**Due Date**

**Status**

**Actual Work 0**

**Completion Date**

**Percent 0  
Complete**

**Requested By**

**Assigned To**

**Current Design:**

**Original US#: 0**

**Category:**

**In Phase 1?: ☐**

**Backlog Type: ☐**

**Category Type: ☐**

### Description

As a user of the HABIT-II HealthCOM portal, I need to be able to see Demographics and Medical History information to be able to put the results of BNP, weight and symptoms data into context. Data to be pulled from the CRF and displayed are: · Site ID 0000 · Subject ID 000 · Meter ID · Randomization arm (if appropriate - HABIT-II will not use randomization to multiple arms, but later studies will) · Age · Sex (M/F) · Height (cm or inches) · Weight (Kg or Lbs) · %LVEF · AFIB y/n · Blood Pressure (sp/dp) · Diabetes y/n · Angina y/n · CAD y/n · COPD y/n · CRT y/n · Hyperlipidemia y/n · Hypertension y/n · Prior MI y/n · Alcohol or drug abuse y/n · Other arrhythmia or tachycardia y/n

## Feature Details

**ID 108****Project HealthCOM2-HABIT-II****Title BNP Graphics**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	
<b>Current Design:</b>	<b>Original US#:</b> 0	<b>Category:</b>
<b>In Phase 1?:</b> <input type="checkbox"/>	<b>Backlog Type:</b> <input type="checkbox"/>	<b>Category Type:</b> <input type="checkbox"/>

**Description**

As a user of the HABIT-II HealthCOM portal, I need to be able to see BNP graphed in a convenient and easy to understand way. • Daily BNP measures should be plotted with a point to point line connecting them. Συμβολ σιζε σηουλδ βε σμαλλ ανδ λινε ιντενσιτυ λιγητ ορ δοττεδ.

- A Kalam data filter is applied to smooth the data (similar to a moving average of the data). The smoothed line should be plotted in a greater intensity than the point to point lines. (Details regarding the Kalam filter provided by Alere San Diego)
- BNP Alerts generated from the BNP data are plotted and some way to distinguish which alert was flagged (color, symbol, text, etc.) is included.
- Study endpoints HF-Death and HF-Hospitalization and Clinical Decompensation are plotted.
- Failed BNP tests resulting in error messages are plotted.
- Y-Axis min and max can be changed by user.
- Define default Y-Axis: 0-intercept to highest point + 10% (?)

**ID 109****Project HealthCOM2-HABIT-II****Title WEIGHTS Graphics**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	
<b>Current Design:</b>	<b>Original US#:</b> 0	<b>Category:</b>
<b>In Phase 1?:</b> <input type="checkbox"/>	<b>Backlog Type:</b> <input type="checkbox"/>	<b>Category Type:</b> <input type="checkbox"/>

**Description**

As a user of the HABIT-II HealthCOM portal, I need to be able to see weights graphed in a convenient and easy to understand way. • Daily weight measures should be plotted with a point to point line connecting them. Symbol size should be small and line intensity light or dotted. • No alerts will be programmed for weights • Y-Axis min and max can be changed by user. • Define default Y-Axis: 0-intercept to highest point + 10% (?)

**ID 110****Project HealthCOM2-HABIT-II****Title SYMPTOMS Graphics**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	
<b>Current Design:</b>	<b>Original US#:</b> 0	<b>Category:</b>
<b>In Phase 1?:</b> <input type="checkbox"/>	<b>Backlog Type:</b> <input type="checkbox"/>	<b>Category Type:</b> <input type="checkbox"/>

**Description**

As a user of the HABIT-II HealthCOM portal, I need to be able to see symptoms graphed in a convenient and easy to understand way. • Daily symptoms measures should be plotted and symbols (circles?) should be color coded. No = green, Red = yes • Symptom Alerts generated from the data are plotted and some way to distinguish which alert

## Feature Details

was flagged (color, symbol, text, etc.) is included.

**ID 111**

**Project HealthCOM2-HABIT-II**

**Title KEY HF MEDS Graphics**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	
<b>Current Design:</b>	<b>Original US#:</b> 0	<b>Category:</b>
<b>In Phase 1?:</b> <input type="checkbox"/>	<b>Backlog Type:</b> <input type="checkbox"/>	<b>Category Type:</b> <input type="checkbox"/>

### Description

As a user of the HABIT-II HealthCOM portal, I need to be able to see key heart failure medications graphed in a convenient and easy to understand way. · Daily doses should be calculated from the data in the CRF (dose x frequency) plotted each day in a manor such that changes in daily dose are easily identified in the graphs and the Rx regimen can be followed over time. · Key oral and IV HF Meds: o All Diuretics (Loop, Thiazide, potassium sparing, etc.) o Beta Blockers o ACE-Inhibitors o ARBs (Angiotensin Receptor Blockers) o Aldosterone Antagonists o Steroids o Vasodilators

**ID 112**

**Project HealthCOM2-HABIT-II**

**Title Data Tables**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	
<b>Current Design:</b>	<b>Original US#:</b> 0	<b>Category:</b>
<b>In Phase 1?:</b> <input type="checkbox"/>	<b>Backlog Type:</b> <input type="checkbox"/>	<b>Category Type:</b> <input type="checkbox"/>

### Description

As a user of the HABIT-II HealthCOM portal, I need to be able to see some key data as tables in addition to graphics. · BNP Table (From HeartCheck) [date/time local & GMT; BNP; units; alert #] · Weight Table (From HeartCheck) [date/time local & GMT; Weight; units; alert #] · Study Events: [date/time local & GMT; event: clinical decompensation; HF-hospital admission (dates of dmit/discharge); HF-Death (date of death)] · Cardiovascular Medications (Classes of drugs) (from CRF) [date/time local & GMT; drug name; drug class; start date; stop date; dose; frequency; route; reason for change; change based on] o Diuretics (all subgroups Loop, Thiazide, Potassium sparing, etc.) (oral and IV) o ACE-I o Beta Blockers o ARBo Aldosterone antagonistso Vasodilators/ Nitrates/Hydrolazineo Steroids (Glucocorticoid/Corticosteroid/ β2-adrenergic receptor agonist)o Ionotropes (oral and IV)o CCB (Calcium Chanel Blocker)o Cardiotonic agento Digitalis/cardiac glycosideo Anti-arrhythmico Xanthine oxidase inhibitoro Anti-plateleto Statin/Anti-hypertensiveo OATo PPIo Anti-diabetic biguanide · Key Lab Tests (from CRF) [date/time local & GMT; value, units] o Creatinineo Potassiumo Lab derived BNP

**ID 113**

**Project HealthCOM2-HABIT-II**

**Title SEPARATE GRAPH OF STUDY EVENTS**

<b>Build #</b>	<b>Start Date</b>	<b>Priority</b>
<b>Original Work</b> 0	<b>Due Date</b>	<b>Status</b>
<b>Actual Work</b> 0	<b>Completion Date</b>	<b>Percent Complete</b> 0
<b>Requested By</b>	<b>Assigned To</b>	

## Feature Details

Current Design:

In Phase 1?: ☐

Original US#: 0

Backlog Type: ☐

Category:

Category Type: ☐

### Description

As a user of the HABIT-II HealthCOM portal, I need to be able to see a graphic representation of study events. An alternative approach is to graph study endpoints (HF-Death, HF-Hospitalization, and clinical decompensation) as separate graphics distinct from the BNP graphics.

ID 114

Project HealthCOM2-HABIT-II

Title METER ID / SUBJECT ID

Build #

Start Date

Priority

Original Work 0

Due Date

Status

Actual Work 0

Completion Date

Percent Complete 0

Requested By

Assigned To

Current Design:

Original US#: 0

Category:

In Phase 1?: ☐

Backlog Type: ☐

Category Type: ☐

### Description

As a user of the HABIT-II HealthCOM portal, the identity of patients must be protected and all study data must be de-identified in order to meet the regulatory and good clinical practice guidelines. The HeartCheck data is coded by Meter ID. The CRF is coded by Subject ID and contains the Meter ID to link the two sources of information. Meters may be changed during the study, but an updated Meter ID will exist in the CRF.

ID 121

Project HealthCOM2-HABIT-II

Title GRAPHIC SUMMARY

Build #

Start Date

Priority

Original Work 0

Due Date

Status

Actual Work 0

Completion Date

Percent Complete 0

Requested By

Assigned To

Current Design:

Original US#: 0

Category:

In Phase 1?: ☐

Backlog Type: ☐

Category Type: ☐

### Description

Mock-up of graphci summary

ID 122

Project HealthCOM2-HABIT-II

Title HOW IT WORKS FLOWCHART

Build #

Start Date

Priority

Original Work 0

Due Date

Status

Actual Work 0

Completion Date

Percent Complete 0

Requested By

Assigned To

Current Design:

Original US#: 0

Category:

In Phase 1?: ☐

Backlog Type: ☐

Category Type: ☐

### Description

SEE ATTACHEMENT