



Clinical Decision Support – Path to Functional Requirements

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Expanding the Boundaries of Space Medicine and Technology

- **Purpose and Objectives**
- **Defining a Clinical Decision Support System (CDSS) for Exploration**
 - What is a CDSS?
 - What does a CDSS do?
- **CDSS Functional Requirements**
 - Approach
 - Example of software prototype
 - Example of Systems Engineering (SE) artifacts
- **Summary and Conclusion**

Purpose and Objectives



- **NASA-STD-3001 previously presented the need for crew members to operate independently during long duration space exploration missions that require medical Level of Care V**
 - Interpretation of NASA-STD-3001 Levels of Care for Exploration Medical System Development (NASA/TM-2017-219290):
 - Maintains 'autonomous' in the description of capabilities and definitions that pertain to medical Level of Care V.
- **Computational and data resources will play an important role in maintaining crew health, wellness and performance where the crew will need to be more self-reliant.**
 - Communication lags (~ 20min each way on a Mars mission)
 - Communication blackouts, planned and unplanned
 - No resupply
 - No evacuation
 - Potential limited knowledge, skills and ability (KSA)
 - Skills erosion over time
 - Crew time limited to identify symptoms, collect data, apply solutions and problem solve



Clinical Decision Support Objective



ExMC Element Risk:

Risk of Adverse Health Outcomes & Decrements in Performance due to Inflight Medical Conditions

Clinical Decision Support (CDS) Project Need:

ExMC Gap Medical-701: Enhance medical capabilities within an exploration medical system.

CDS Project Goal:

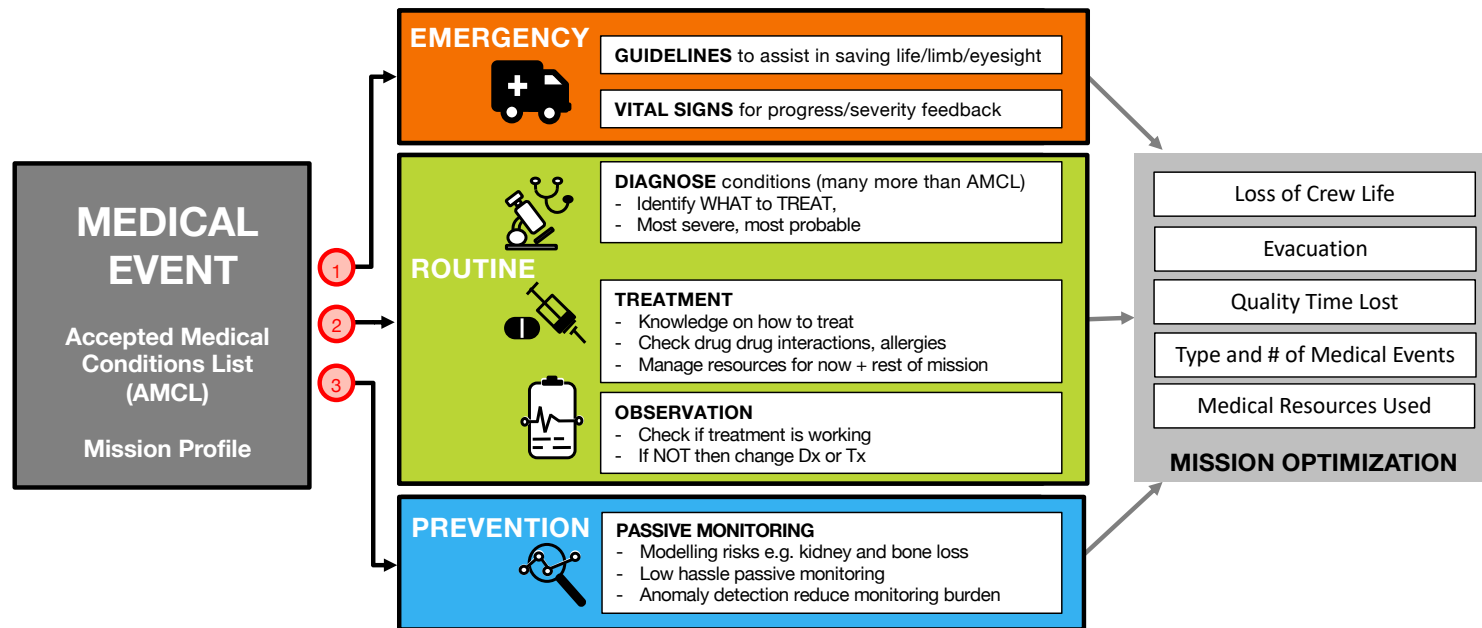
The aim of the CDS project is to [develop and provide recommended functional requirements](#) for an in-vehicle CDSS that [acts as an assistant](#) for delivering optimal health and performance and medical care during exploration missions.



Clinical Decision Support System



Why	Autonomy is required with reduced communication leading to less immediate support from the ground . Mission risk is reduced with medically healthy crew . Resources are limited: knowledge, skills, abilities, time, supplies . CDSS augments limited resources by assisting decision making, increasing clinical practice levels of the crew and reducing mass, volume and power for the mission increasing mission success criteria, i.e., optimize mission goals.
What	The CDSS is a software tool on a laptop and/or onboard system that interacts with the crew, databases (e.g., medical/clinical procedure, pharmacy, wellness, schedule), instruments (e.g., ultrasound, automated external defibrillator or AED, blood labs), and vehicle systems (e.g., environmental, communication).
Where	The CDSS is used in the vehicle, enabling ground support and possibly extravehicular activity (EVA) suits/vehicle.
Who	The crew approaches and utilizes CDSS from different individual perspectives of knowledge, skills and abilities . Ground support will also leverage CDSS information and coordination of effort in support of crew activities.
When	There are three types of generalizable medical situations (each with unique requirements) that the CDSS must support: Emergency – save life, limb or eyesight immediately Routine – ranging from simple to complex differential diagnosis and treatment Preventative – high-yield reduction of long0-term risk buy down
How	Various devices using keyboard, screen contact and non-contact (e.g., video/RF, motion/activity pattern analysis data capture, etc.) of crew/system actions/interactions , show relevant only information to aid focus, advanced monitoring with artificial intelligence (AI) models using webcam, audio, keyboard, external systems (e.g., vehicle lighting, sensors).



3 different scenarios need different approach to assistance

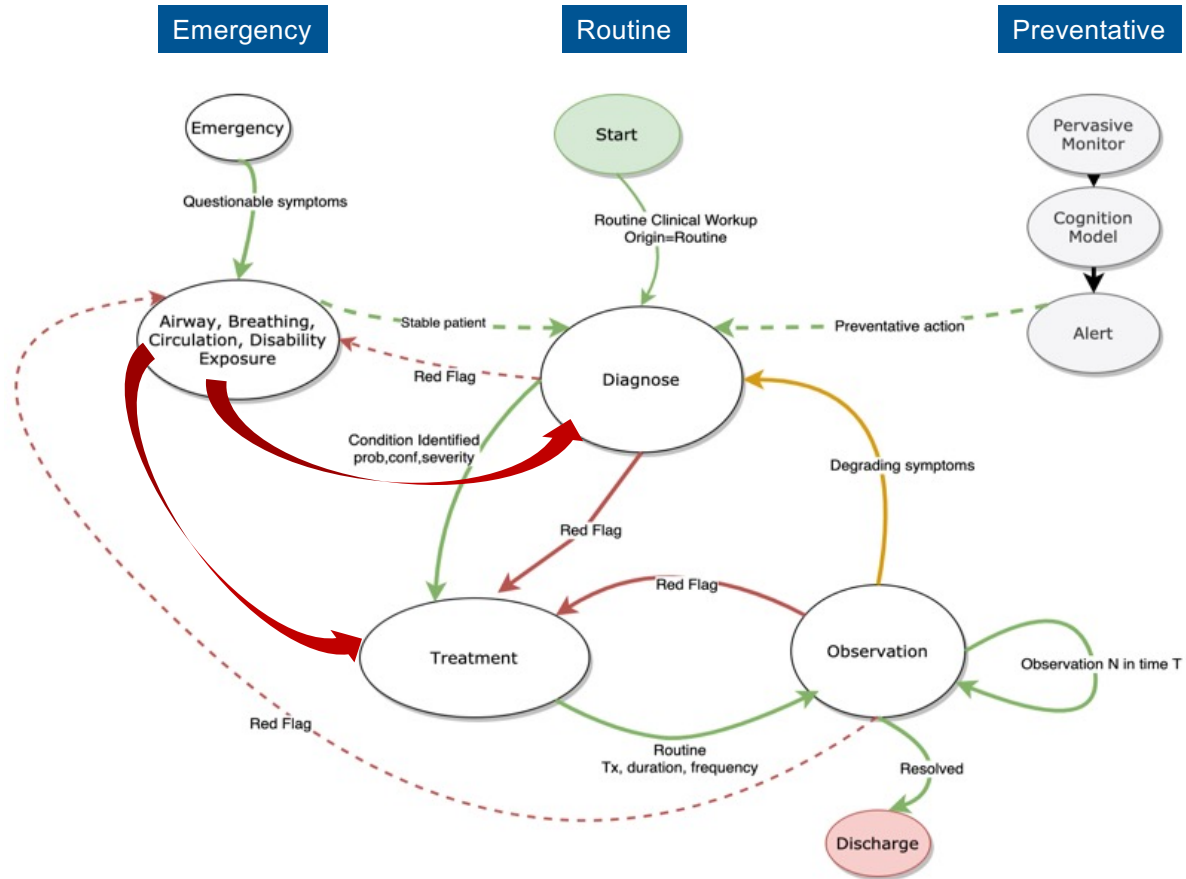
Note:

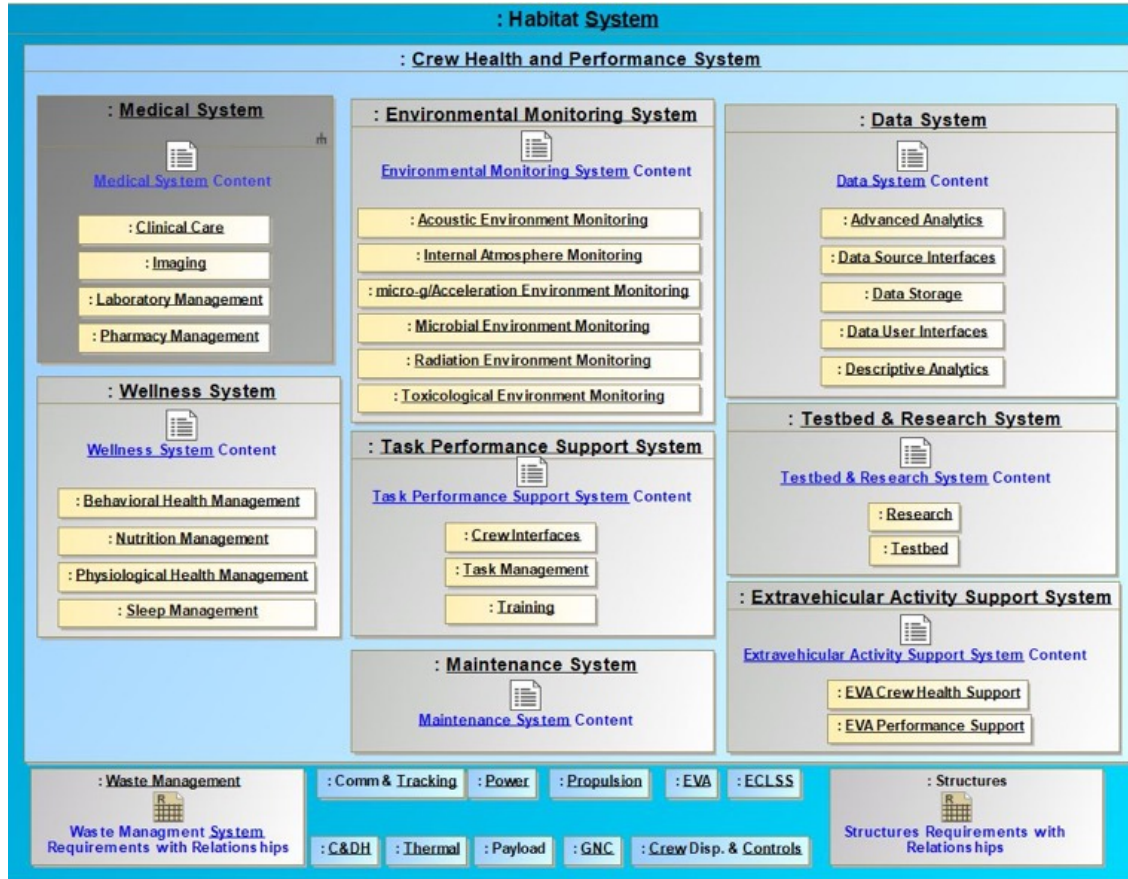
Dx - Diagnosis
Tx - Treatment

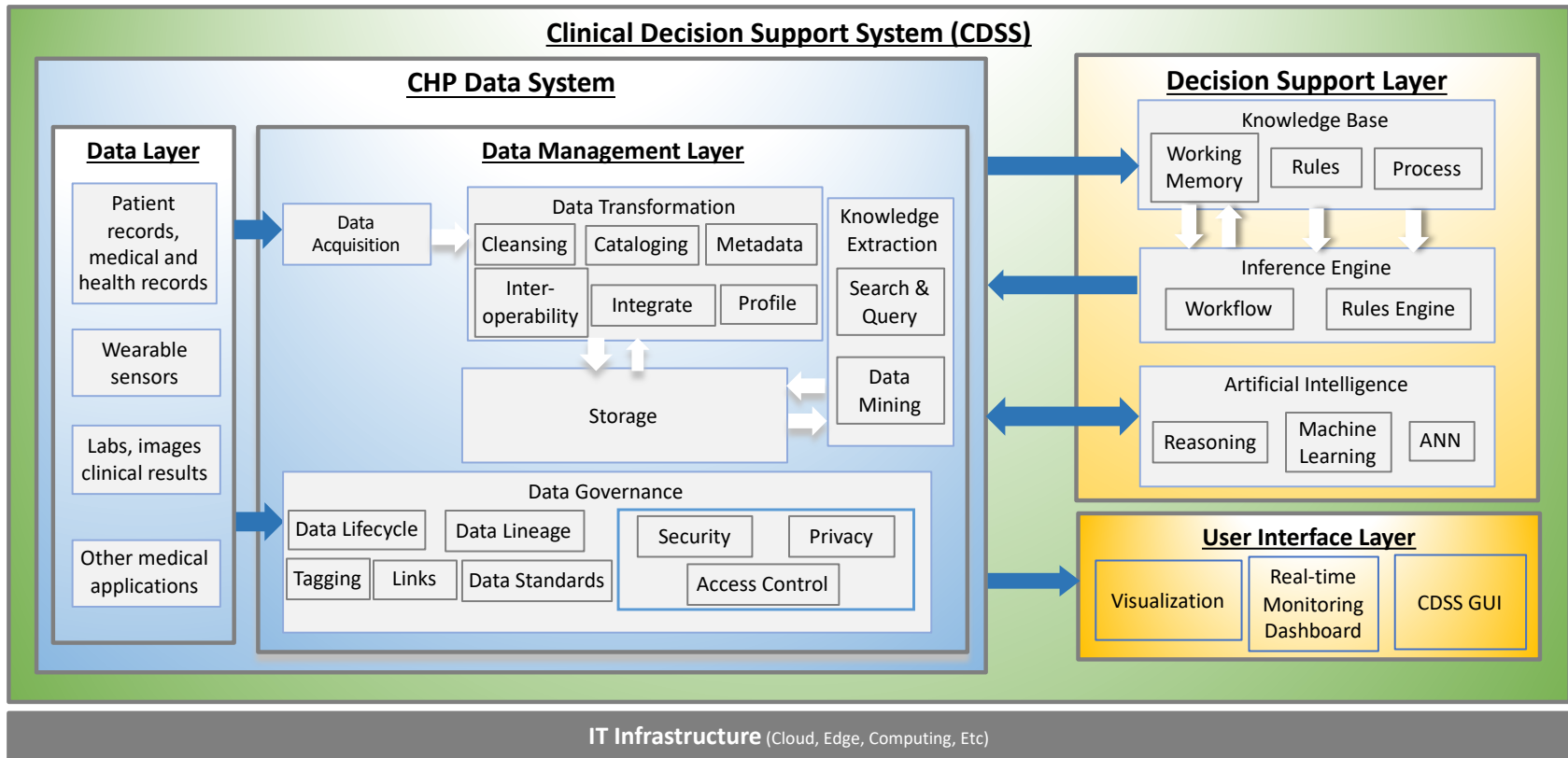
Scope

Implement

Goals



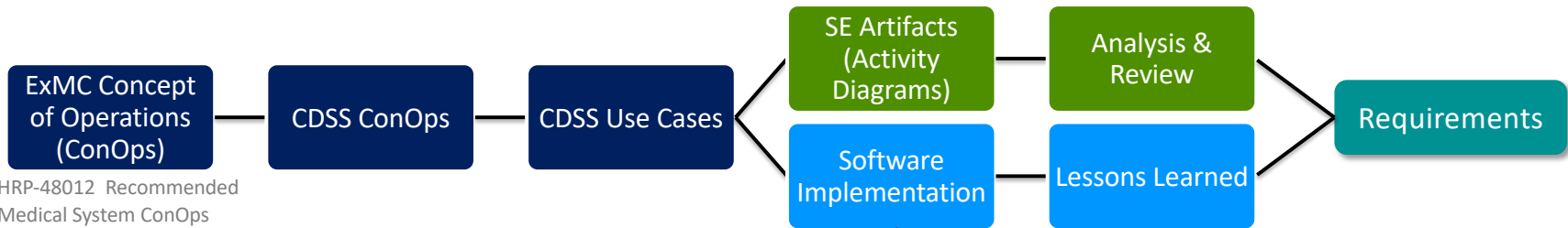






CDSS Requirements Development

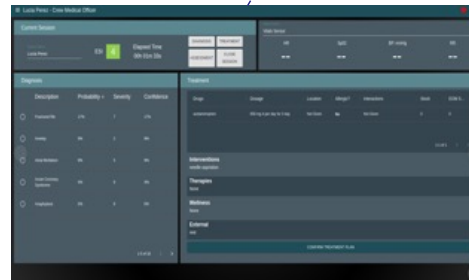




- HRP-48012 Recommended Medical System ConOps
- JSC-67070 Medical System ConOps Mars Missions, pre-Baseline



Diagnosis



Treatment



Emergent Scenario

Epic 2 Summary:

Treatment with a new dashboard added to the existing user interface (UI), model, drug interactions and allergies, from the patient's electronic health record (EHR).

Benefits/Questions

Clinical: Provide pharma information to CM/CMO

Science: Treatment model adaptation for pharma

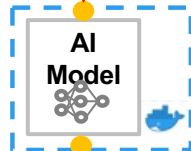
Technical: How to assist all treatable conditions?

How to manage: pharmacy stock levels, drug interactions, allergies?

1. User Interface



2. Models



3. Architecture



4. Data



Database Knowledgebase



Use Case SE Functional Decomposition

Use Case Software Functional Decomposition

Implementation Tasks:

- Develop treatment model and knowledge base
- Develop treatment GUI¹/API²
- Expand treatment model to provide pharma recommendation
- Incorporate EHR data such as crew allergies
- Incorporate pharma data such as side effects

Potential Requirements

The CDSS shall:

- display treatment model results
- display a pharmaceutical recommendation
- display pharmacy information
- contain a treatment model
- include pharmaceutical treatment options
- include non pharmaceutical treatment options
- trade off pharmacy levels
- calculate drug interactions
- determine allergies
- manage 100's of symptoms and conditions
- retrieve pharmacy datasets
- retrieve personal health records

Lesson Learned

¹GUI – Graphical User Interface

²API – Application Programming Interface

Epic 2 Summary:

Treatment with a new dashboard added to the existing UI, model, drug interactions and allergies (from the patient's EHR).

Implementation Tasks:

- Develop treatment model and knowledge base
- **Develop treatment GUI/API**
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Lessons Learned:

- Delphi-derived knowledge base w/probabilistic model to scale problem (Dx, Tx)
- **Information display (drug, intervention, wellness, observation), (stock levels, allergies, dosage)**
- **Data required, future use trade-off, AI model extensibility**
- Determine patient categories of data to provide a safe Tx recommendation
- **How does pharmacy specialty present/use interaction data**

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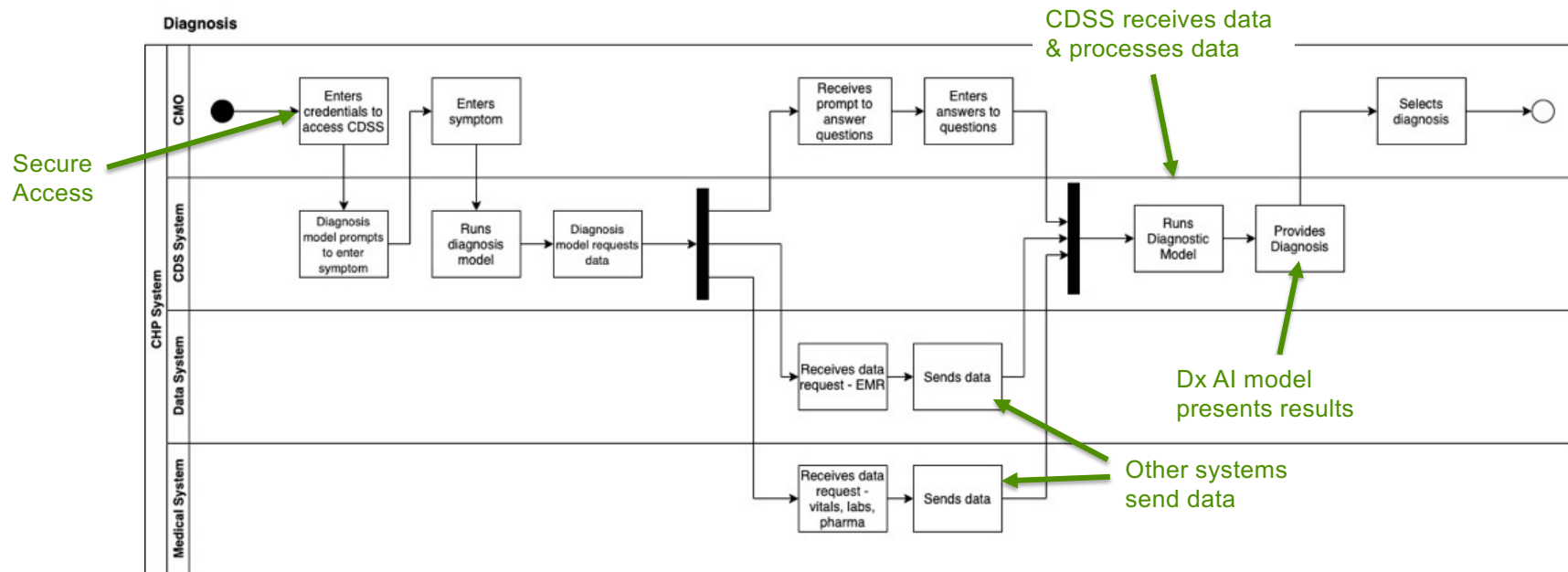
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*Software Functional
Decomposition*



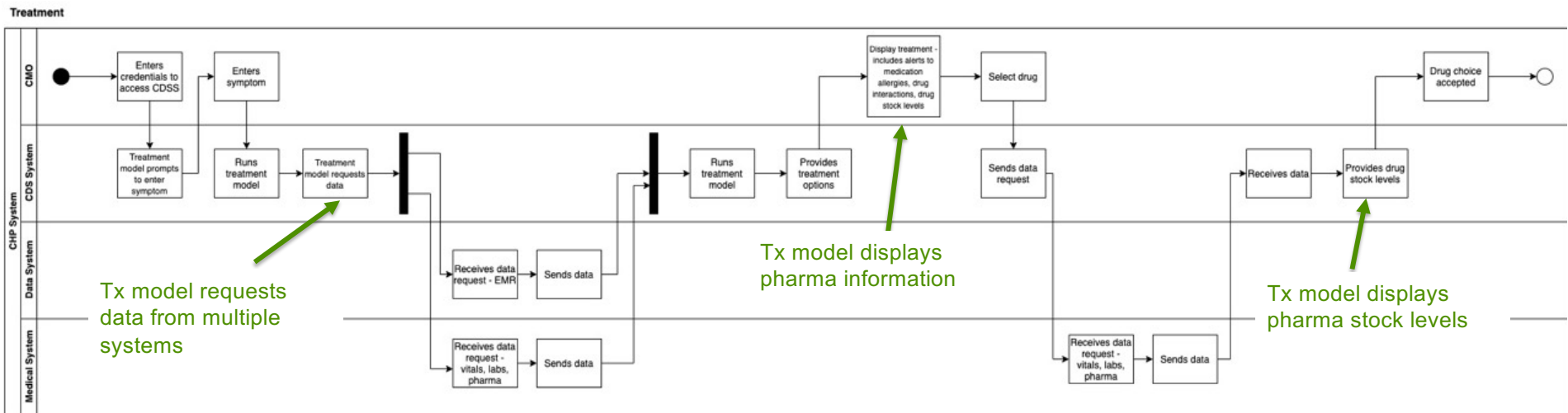
DIAGNOSIS

- Start with ExMC ConOps, CDSS ConOps and CDSS Use Cases
- Generate activity diagrams
- Identify functionality



TREATMENT

- Start with ExMC ConOps, CDSS ConOps and CDSS Use Cases
- Generate activity diagrams
- Identify functionality





Summary and Conclusion



- **The basis for CDSS requirements provided by:**
 - Software prototypes of increasing complexity
 - Functional decomposition of the CDSS ConOps and use cases
 - Activity diagrams
- **Software implementation lessons learned defined:**
 - Broad areas of requirements
 - Specific requirements
- **Functional decomposition and activity diagrams yielded additional specific requirements.**
- **Further analysis of the SE products and lessons learned identified specific capability that resulted in the drafted set of functional requirements provided in FY21.**

Documentation/SysML Models

- Deliver CDSS architecture recommendation document (HRP-48032), Rev A
- Deliver CDSS Systems Modeling Language (SysML) model that contains:
 - Rev A CDSS concept of operations document (HRP-48033)
 - CDSS Functional requirements
- Deliver updated Data System Model that contains:
 - CHP Integrated Data System Requirements (HRP-48034, HRP-48035) revision (L4.1 requirements for Medical Level of Care IV, V)
- Publish space exploration CDS paper in a peer-reviewed journal
- Update and archive other associated CDS Project documentation
 - Use Case document, Program Management Plan, Software Engineering Management Plan, etc.

Implementation

- Develop a CDSS app demonstration
- Archive CDSS code developed for software implementation, including decision-making algorithms/models for diagnosis, treatment and observation

The screenshot shows a web browser window displaying the 'CHP Habitat Data System Model' report. At the top, there are navigation links: '<HomePage>', 'Content Diagram', 'For HTML Report', and 'Home'. The main heading is 'CHP Habitat Data System Model'. Below this is a section titled 'About this HTML Report' which explains that the report contains visualizations and links for the CHP Habitat Data System for Level 4.1 Functional Requirements. A large blue box labeled 'Model Directory' contains a central white box for 'Requirements' with a document icon and the text 'CHP Habitat Data System Requirements'. Below the directory box is an 'Additional Content' section with links for 'Testbed Requirements and Tracing Overview' and 'Architecture Overview'. The 'Purpose & Scope' section follows, with a note that it lists purpose, scope, and change authority, and includes three document icons labeled '01_01_Purpose', '01_02_Scope', and '01_03_Change Authority'. At the bottom, there is a 'CHP Habitat Data Glossary and Acronyms' section with a document icon, and a 'Contact' section listing System Engineer Jeremy Noel with his email 'ejeremy.noel@nasa.gov', version '1.0 (Branch 44)', and last updated date 'September 2, 2021'.