



Exploration Medical Capability Systems Engineering Overview and Update

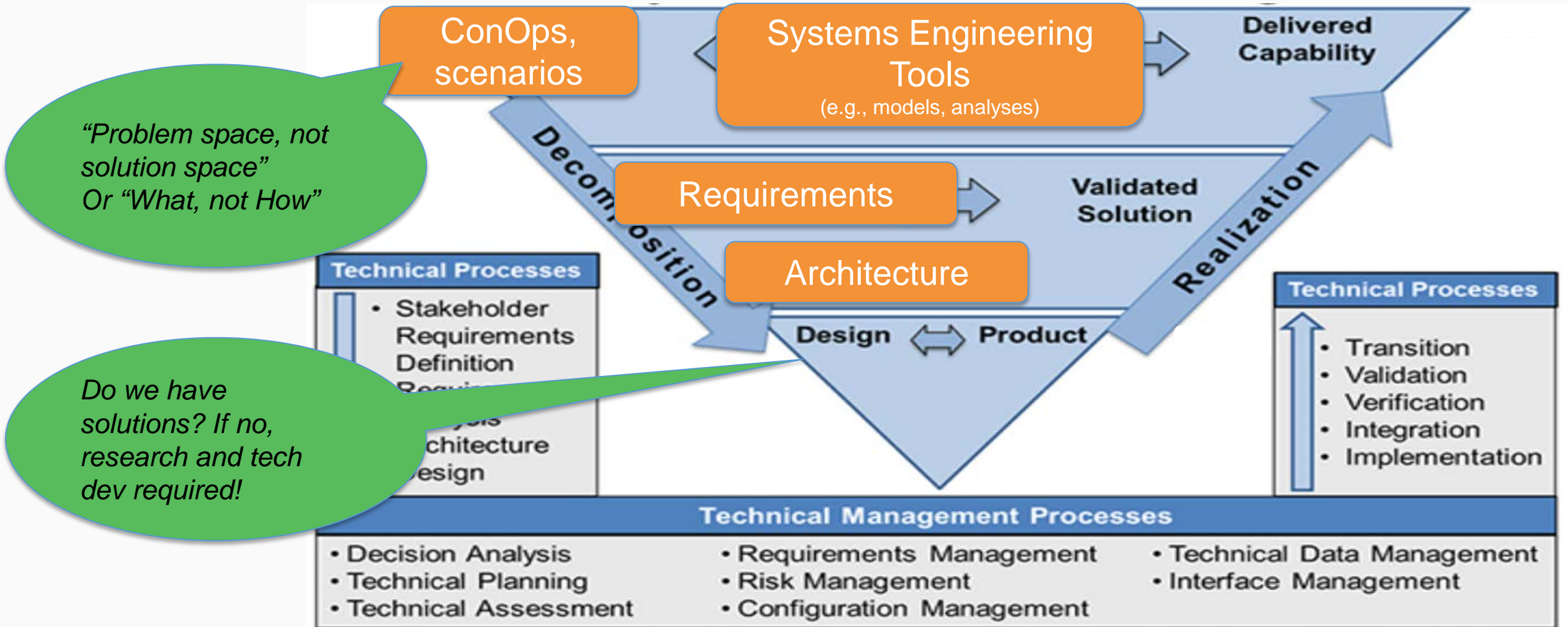
Jennifer Mindock
Michelle Urbina
Kerry McGuire

2019 NASA Human Research Program Investigators' Workshop
January 22 - 25, 2019 | Galveston Island Convention Center

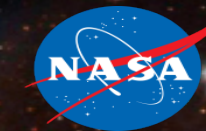
Why Systems Engineering?



We must communicate with exploration mission development activities effectively



ExMC SE Mission – 2+ years later still holds



Define, develop, validate, and manage the technical system design needed to implement exploration medical capabilities for Mars and test the design in a progression of proving grounds.

Needs

Develop system technical foundation

- Develop ConOps
- Capture stakeholder expectations
- Define and manage requirements
- Capture and share system design
- Identify and manage cross-disciplinary interfaces
- Plan and execute system
- Inform system development from scientific, technical perspective
- Identify tech dev and research needs

Approach

Apply structured, integrative science and engineering

- Use a structured and disciplined approach to develop a med system addressing medical, behavioral health, human factors, physiological performance, and task performance needs to ensure crew health and integration with exploration mission engineering, operational, and technology development efforts

Benefit

Increase relevancy to exploration system maturation

- Speak the same language as engineering and operations communities with respect to system design
- Provide regular and transparent communication to maintain insight into the med system development
- Develop and foster shared mental models within and external to crew health and performance community

Culture

Be open, unbiased, learning, and serving

- Develop relationships across disciplines and Centers to build trust and enable teamwork
- Enhance visibility and opportunities for influence on concurrent activities of related groups that otherwise would
- Be both responsive to and anticipatory of stakeholder needs, keeping in mind stakeholders may be from anywhere in an org chart

See our Systems Engineering Management Plan (SEMP)!

Growth



Late FY16

FY17

FY18

FY19

**Team members:
(not full time)**

4

11

> 30

**Example
Products:**

- Systems Engineering Mgmt Plan...

- Team infrastructure
- Mars transit medical ConOps
- Prototype SysML model
- System needs and goals
- Initial system functions
- Initial system description...

- Expanded team infrastructure
- Lunar vicinity Level 4 med ConOps
- Lunar vicinity med SysML model
- Lunar vicinity med system needs and goals
- Lunar vicinity med system functions
- Lunar vicinity med system description
- Lunar vicinity med conditions list
- Lunar vicinity planned and unplanned med capabilities
- Lunar vicinity draft med system functional requirements
- Medical system trade study tools pilot
- ...

Collaborations:

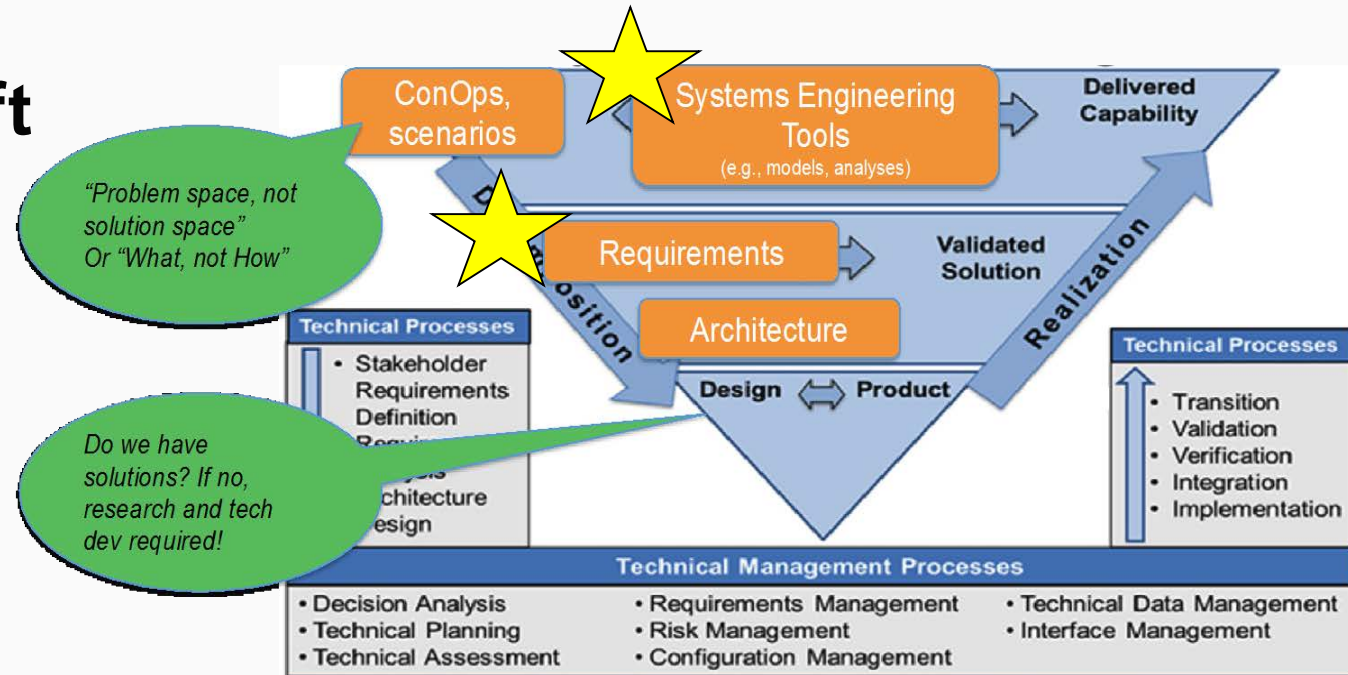
- JSC SD, SF, SK

- ARC, GRC, LaRC
- SMT, CSA, ESA
- iPAS (JSC Engineering)
- MBSE – JSC, NASA
- JSC SD, SF, SK
- ECLSS, Avionics

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- SMT, CSA, ESA
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- MBSE – JSC, NASA
- JSC SD, SF, SK
- ECLSS, Avionics
- HRP PSMO, Elements
- Gateway, Exploration

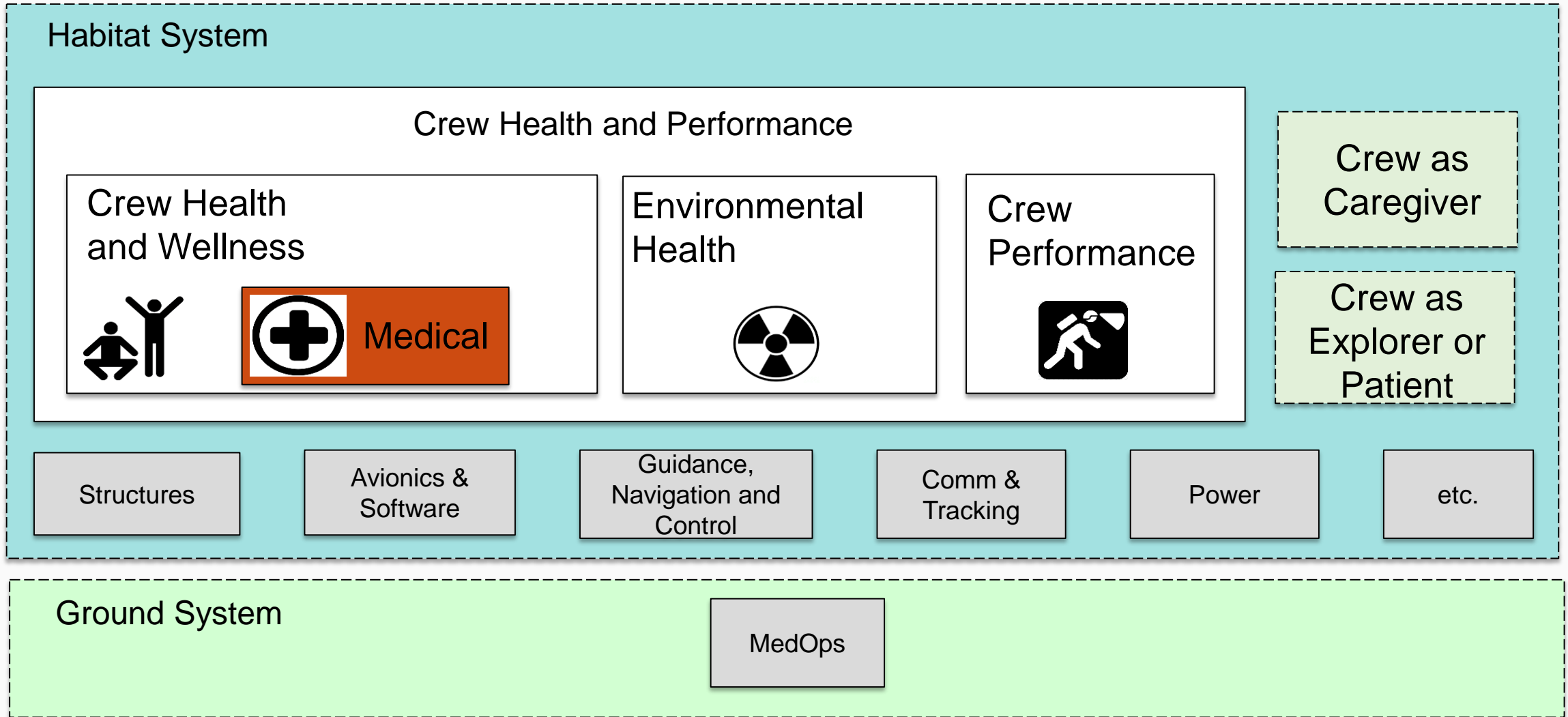
1. Habitat Medical System Draft Functional Requirements

1. Systems Engineering Tools Maturation



<https://map.dau.mil/aquipedia/Pages/ArticleDetails.aspx?aid=9c591ad6-8f69-49dd-a61d-4096e7b3086c>

Applying Systems Engineering to Integrate – Context in Representative System

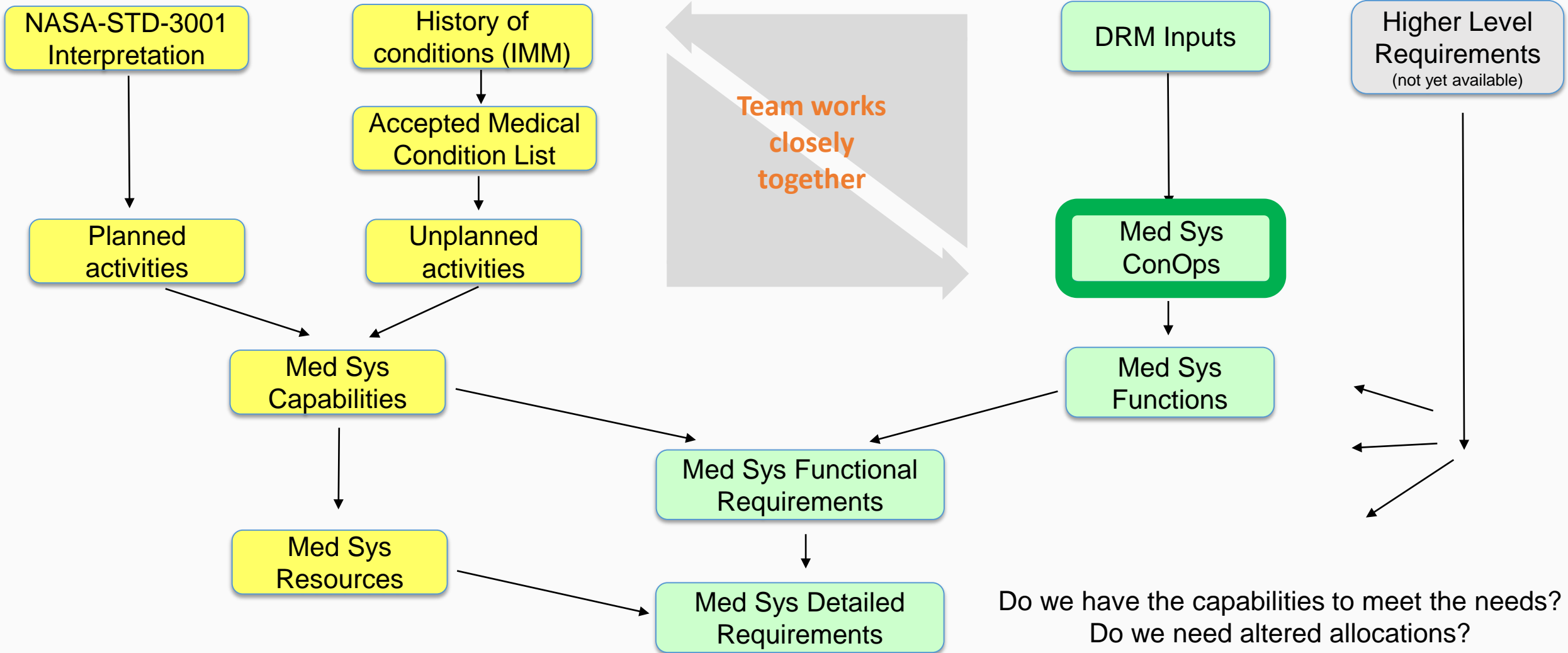


Team activities to get to requirements



Medical Domain Activities

Sys Eng Activities





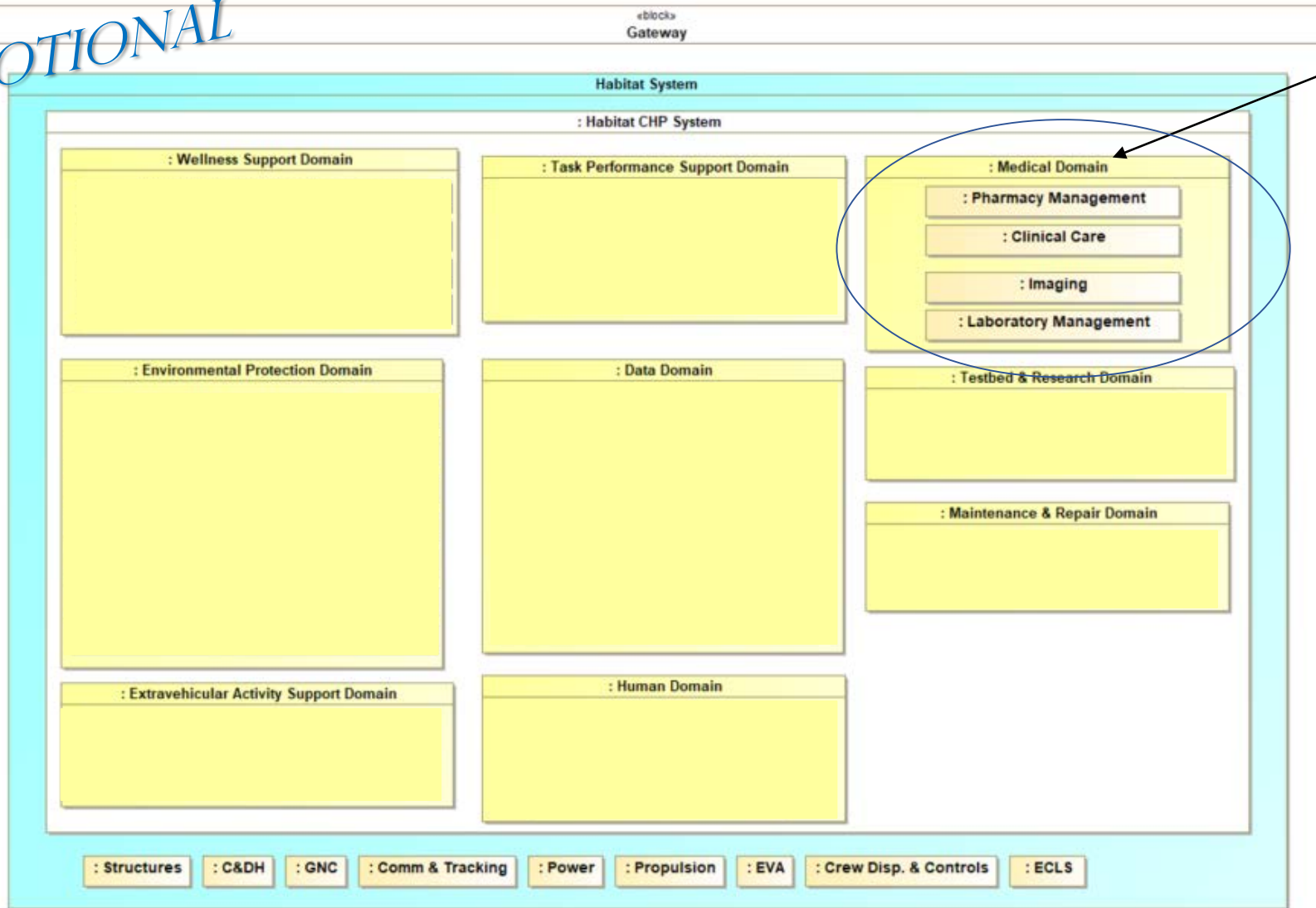
- Provides a **vision** for the system within the design reference mission of interest
- Defines the problem space, not solution
- Informs the ExMC systems engineering effort, providing a foundation
 - on which human-centered activities should be developed
 - used to derive system functions & requirements for the medical system.

See IWS talk on the ConOps development!

Architecture in ConOps and system model



NOTIONAL



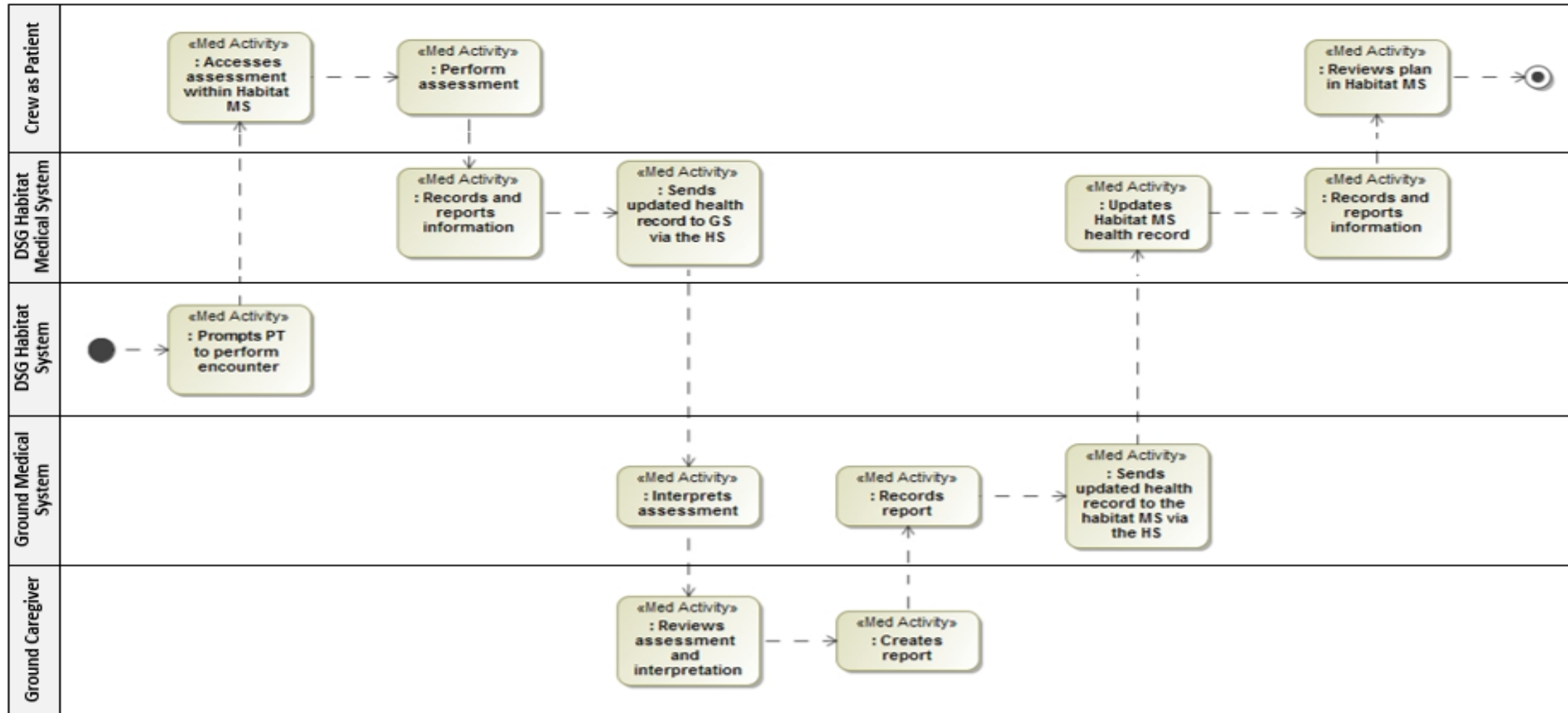
The Medical System architecture defines subsystems/subdomains and gives the framework for requirements, which then evolve into the solutions (hardware/software resources) for implementation.

Example system description:

Subdomain	Description
Clinical Care	Provides in-flight capabilities for the prevention, diagnosis, treatment, monitoring, and long-term management of medical conditions.
Imaging	Provides in-flight capabilities for diagnostic imaging in support of the provision of clinical care. Includes all hardware, software, and analysis capabilities required for the capturing and processing of diagnostic images.
Laboratory Management	Provides in-flight capabilities for laboratory analysis in support of the provision of clinical care. Includes all hardware, software, and analysis capabilities required for the collection and processing of biological samples.
Pharmacy Management	Provides in-flight capabilities for the administration of pharmaceuticals in support of clinical care. Includes all medications and the mechanisms used to prepare and deliver them and track their use.

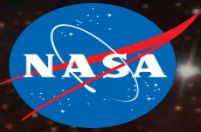
- Allows team to iterate and converge on same understanding of system architecture
- Supports negotiating interfaces between elements

ConOps content in system model

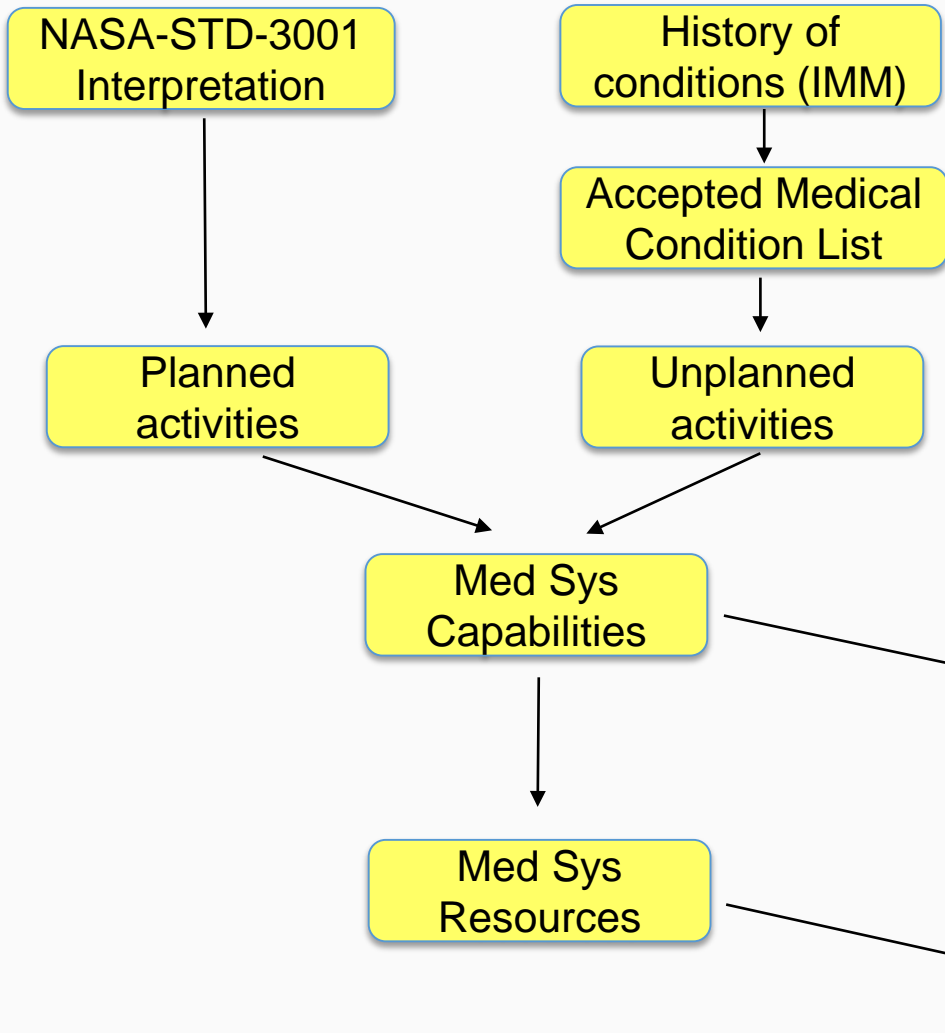


- Team converges on same understanding of behavior and terminology
- Analysis of scenarios supports identification of needed functions

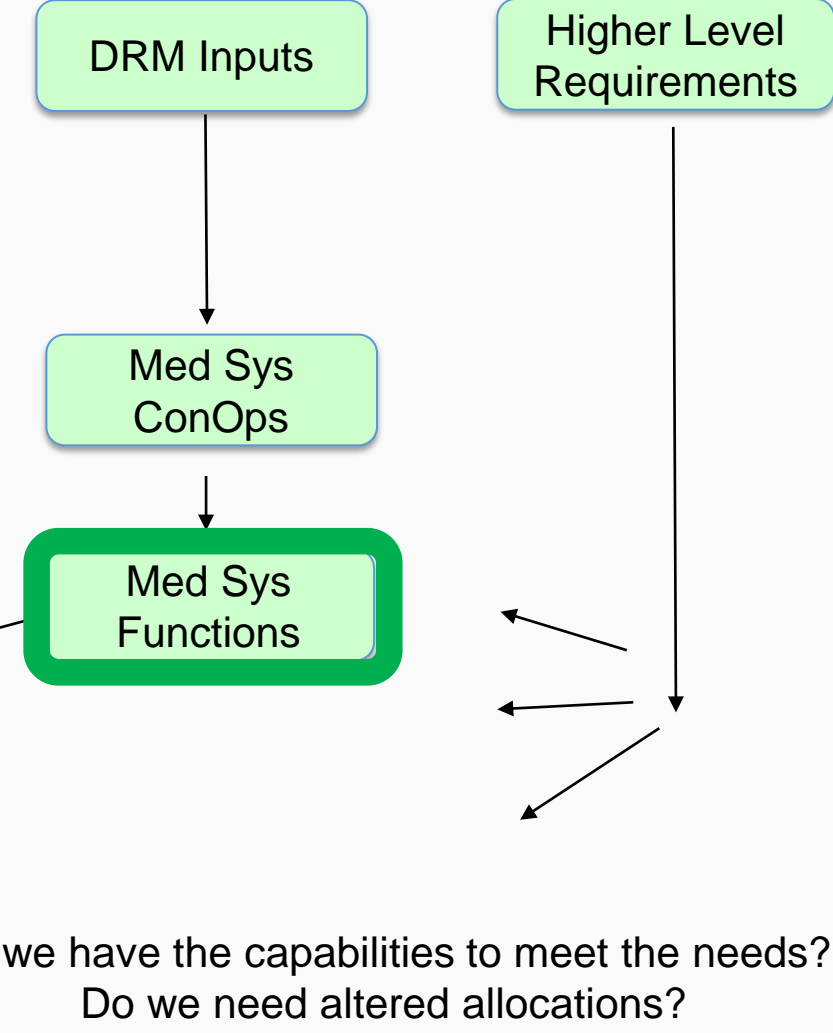
Team activities to get to requirements



Medical Domain Activities

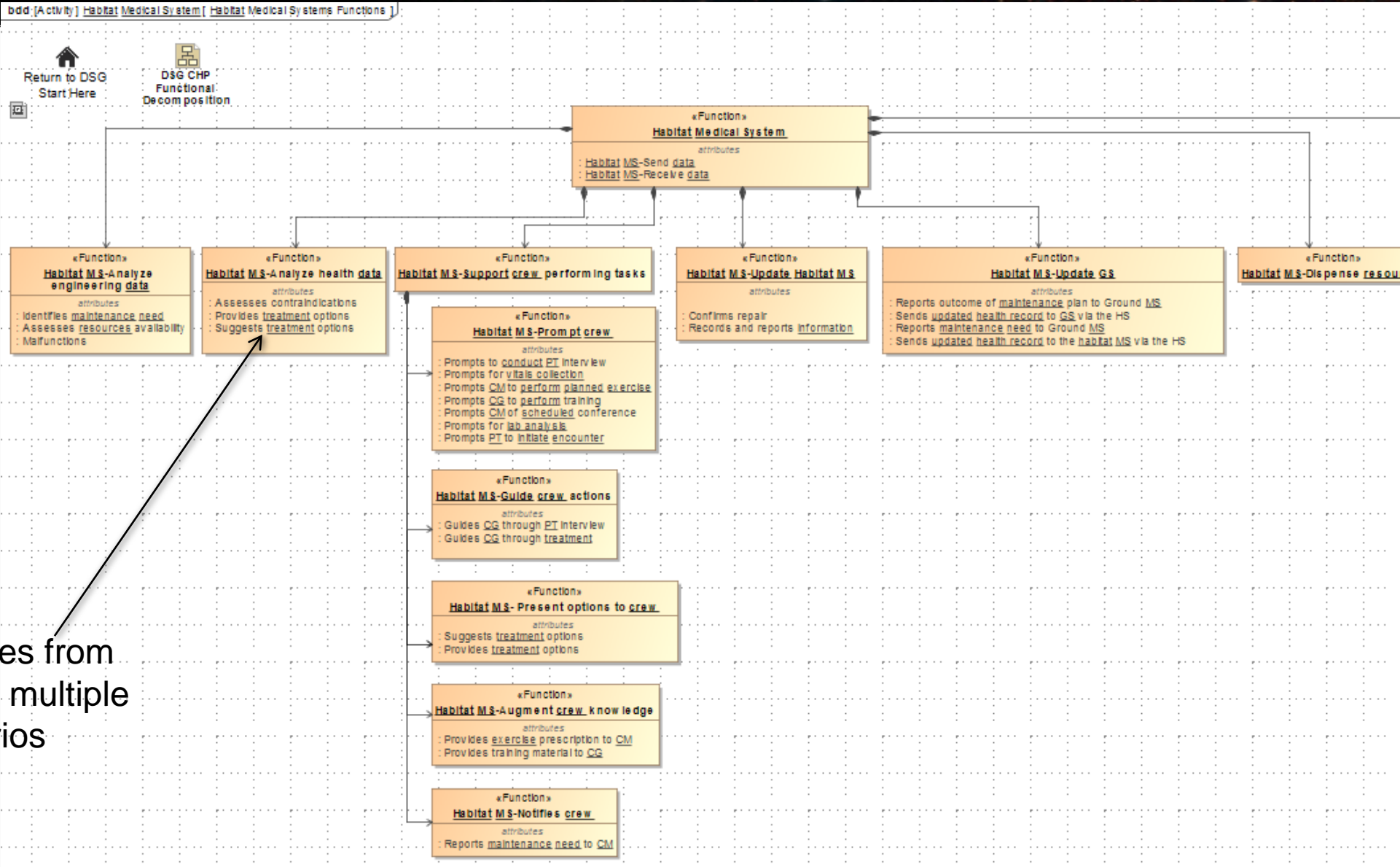


Sys Eng Activities



Do we have the capabilities to meet the needs?
Do we need altered allocations?

Thematic Analysis¹ → Medical System Functions



Activities from across multiple scenarios

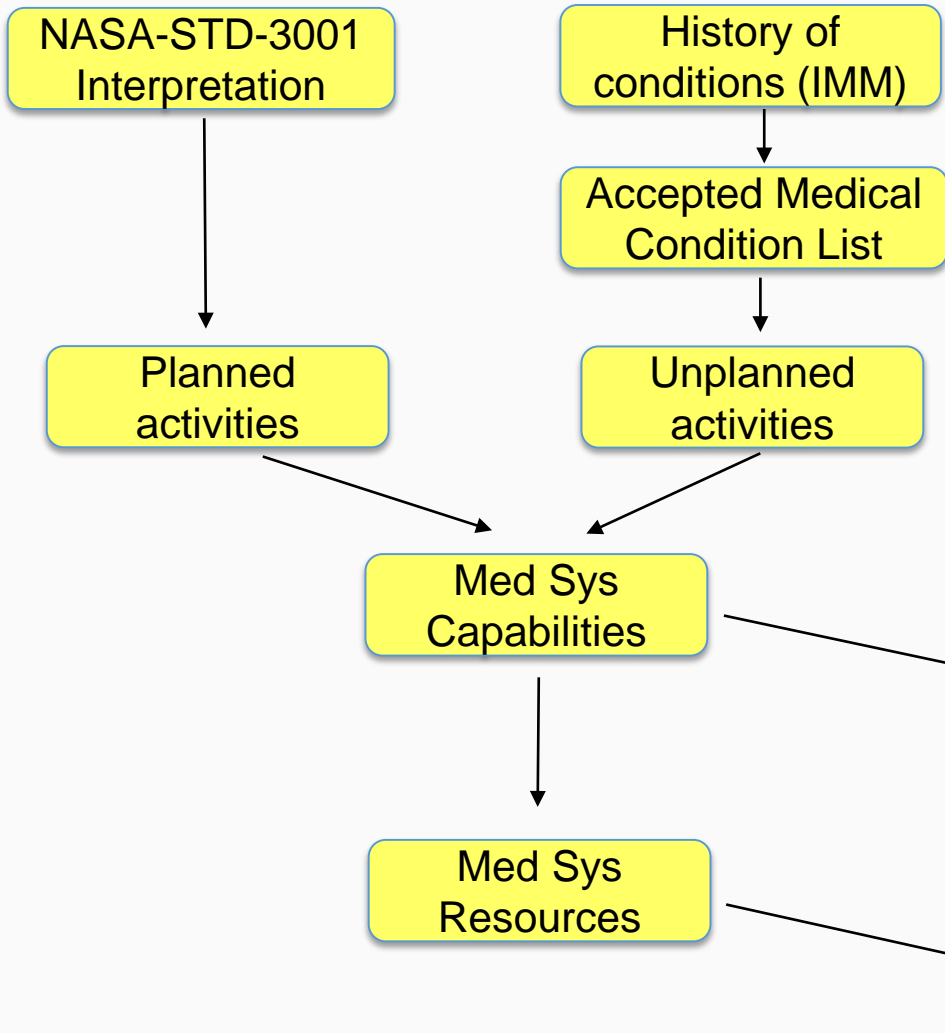
K. McGuire

¹V. Braun, & V. Clark.. Using thematic analysis in psychology. Qualitative research in psychology, 3(2), 77-101. 2006.

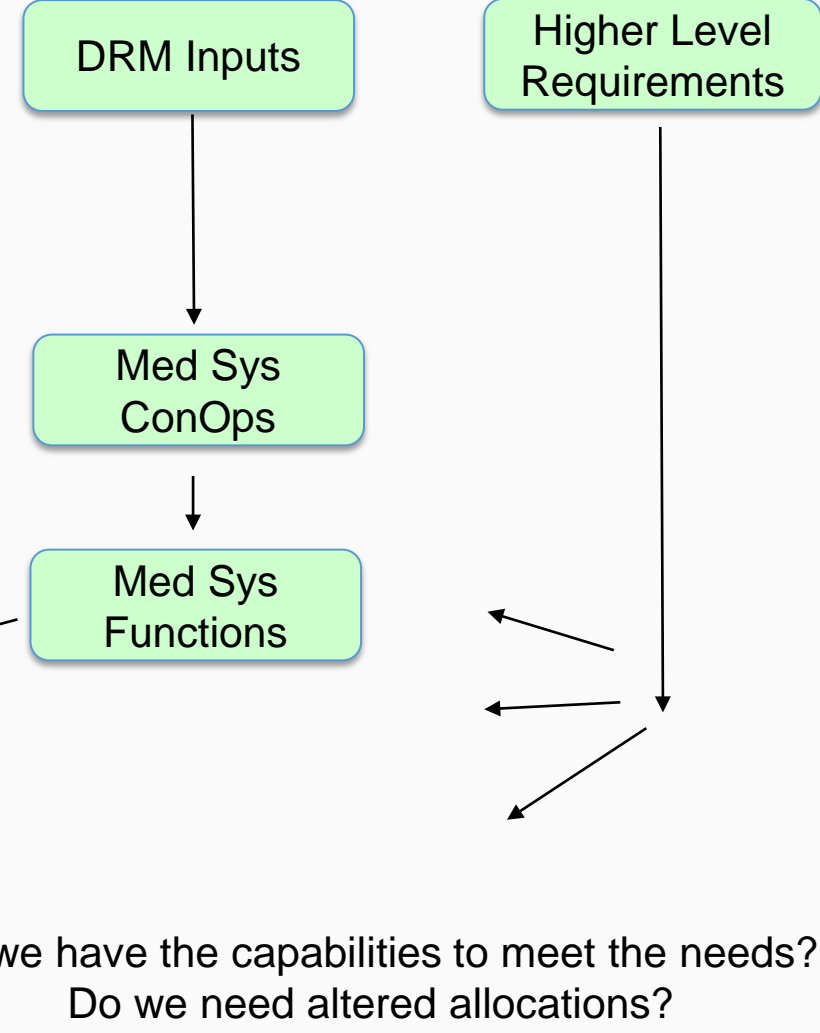
Team activities to get to requirements



Medical Domain Activities



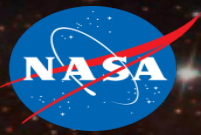
Sys Eng Activities



Do we have the capabilities to meet the needs?
Do we need altered allocations?

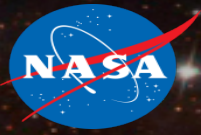
See IWS talk on the requirements development!

Outcome – Functional Requirements in these Categories



- **Provide Appropriate Level of Care**
- **Environment Configuration for Medical Care**
 - Configure Environment for Care
 - Habitat Medical Systems Inventory
- **Knowledge-Based Support for Crew Performing Medical Tasks**
 - Augment Crew Knowledge
 - Analyze Health Data
 - Data Presentation
 - Support Crew Performing Tasks
- **Crew**
 - Crew as Caregiver
 - Crew as Patient
 - Crew as Crewmember
- **Caregiver/Patient Interactions**
 - Interview Patient
 - Perform Physical Exam and Conduct Screening exams/tests
 - Assess and Monitor Vital Signs
 - Administer and Manage Medications
 - Perform Imaging
 - Perform Laboratory Analysis
 - Perform Procedures
 - Personal Protection
- **Medical Assessment and Monitoring**
 - Dietary Control/Nutrition Monitoring
 - Monitor and Assess Environment
 - Monitor and Control Sleep and Fatigue
 - Support Behavioral Health
 - Support Musculoskeletal Health
- **Maintaining Current State of Medical System**
 - Document Care
 - Update Habitat Medical System
 - Analyze Engineering Data
- **In-Flight Prevention**
 - Equipment Procedure
 - Exercise Protocol
 - Hygiene
 - Personal Protection
 - Radiation Exposure
 - Private Conference

Requirements relationships to discipline inputs



Input from clinicians - Capability Category: Perform Imaging

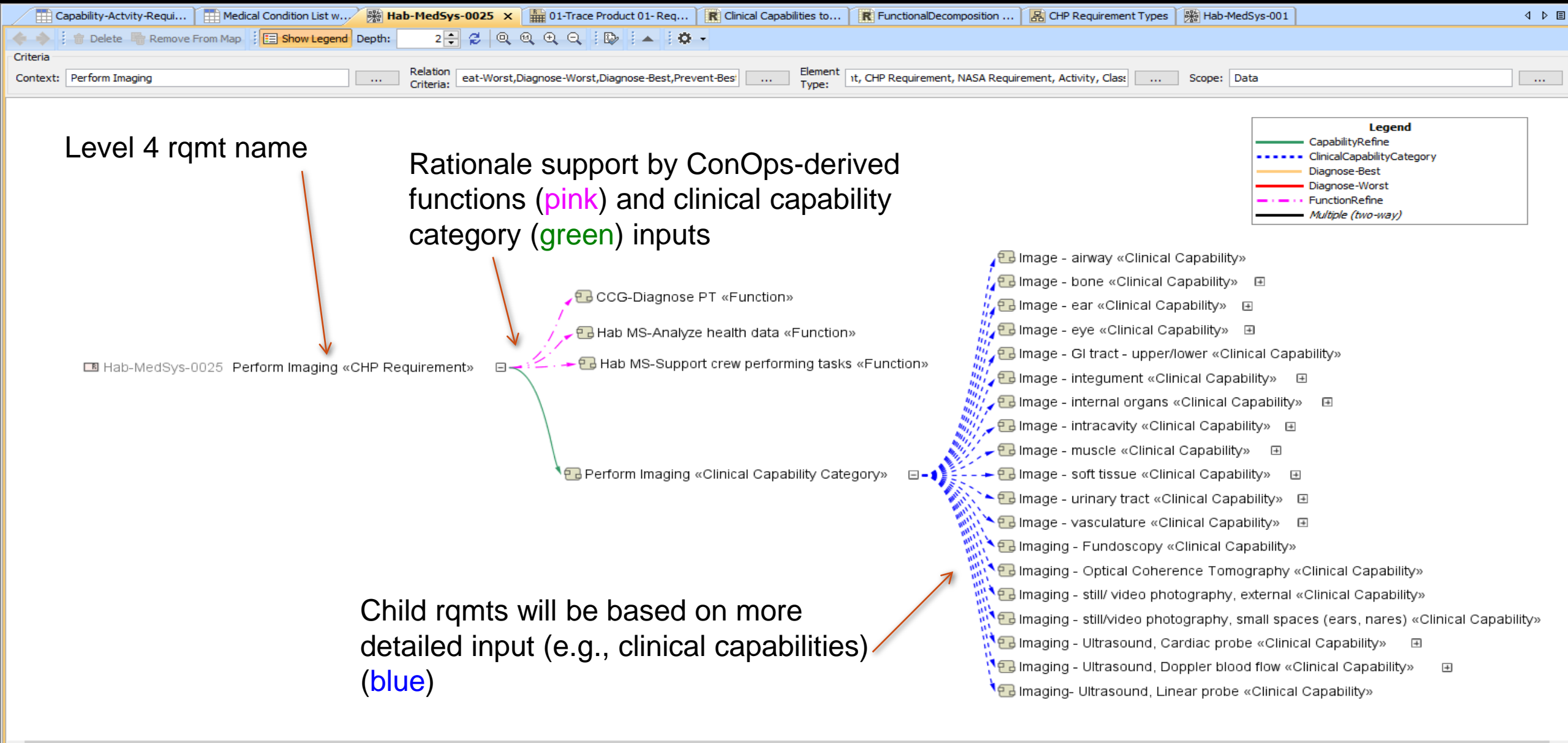
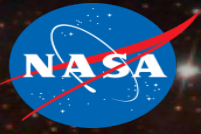
Category	Hab-MedSys-0001	Hab-MedSys-0002	Hab-MedSys-0006	Hab-MedSys-0007	Hab-MedSys-0011	Hab-MedSys-0012	Hab-MedSys-0013	Hab-MedSys-0016	Hab-MedSys-0017	Hab-MedSys-0018	Hab-MedSys-0019	Hab-MedSys-0020	Hab-MedSys-0021	Hab-MedSys-0022	Hab-MedSys-0023	Hab-MedSys-0024	Hab-MedSys-0035	Hab-MedSys-0026	Hab-MedSys-0028	Hab-MedSys-0029	Hab-MedSys-0030	Hab-MedSys-0031	Hab-MedSys-0032	Hab-MedSys-0033	Hab-MedSys-0034	Hab-MedSys-0035	Hab-MedSys-0036	Hab-MedSys-0037	Hab-MedSys-0038	Hab-MedSys-0039	Hab-MedSys-0040
00_Clinical Capability Category	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
Administer and Manage Medications	1																														
Assess and Monitor Vital Signs	5																														
Dietary Control / Nutrition Monitoring	1																														
Document Care	3																														
Interview Patient	1																														
Knowledge Augmentation	5																														
Monitor & Assess Environment	1																														
Monitor and Control Sleep and Fatigue	2																														
Perform Imaging	1																														
Perform Laboratory Analysis	1																														
Perform Physical Exam and Conduct Screening exams/tests	2																														
Perform Procedures	1																														
Support Behavioral Health	1																														
Support Musculoskeletal Health	1																														
01_Clinical Capability	1							3										2	16	6	2	4	6	1	3	3	4	7	1	3	
Configure Environment for Care	1																														
Document Care																															
Interview Patient																															
Perform Procedures								3										2	16	6	2	4	6	1	3	3	4	7	1		
Personal Protection																															
Support Musculoskeletal Health																															3

Output from Rqmts Team - Rqmt: Perform Imaging

Example question for current iteration:
 Are the requirement text and rationale statements a reasonable reflection of intent for the related inputs?

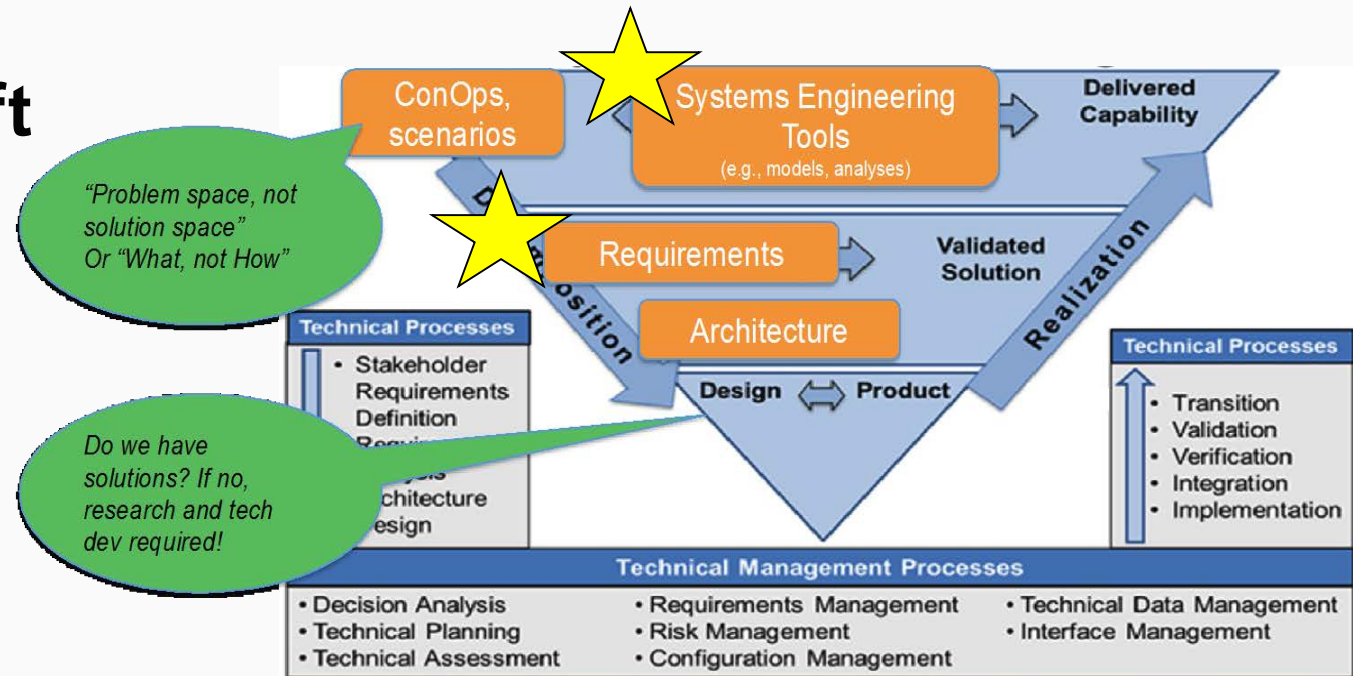
This is building the bridge between SME content and engineering language!

Visualizing the requirement “legs to stand on”



1. Habitat Medical System Draft Functional Requirements

1. Systems Engineering Tools Maturation



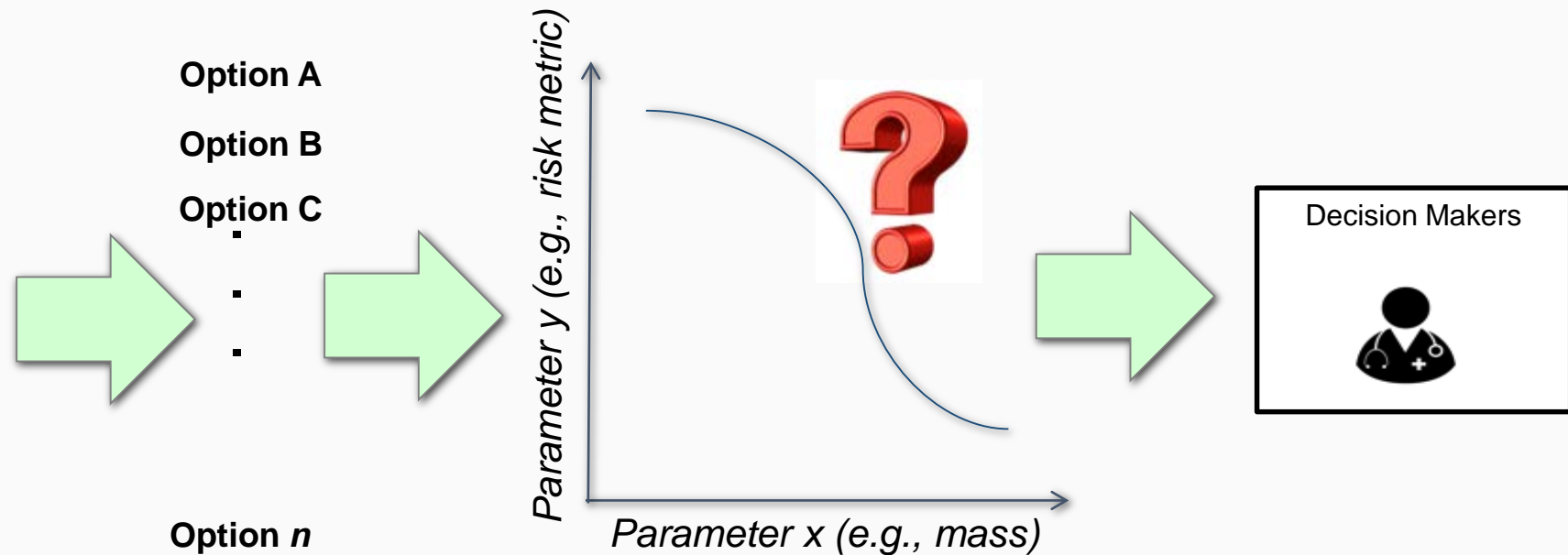
<https://map.dau.mil/aq/pep/ArticleDetails.aspx?aid=9c591ad6-8f69-49dd-a61d-4096e7b3086c>

Trade Space Evaluation Tool Suite – Long-term Goals

- Characterize the exploration medical system architecture trade space to inform mission development, vehicle and habitat development, and research planning.
- For each trade option, characterize medical system parameters relevant to mission decision-makers (e.g., risk metrics, mass).

Trade Option Characterization

- Med conditions addressed
- Standards and rqmts met
- Master equipment list
- Risk evaluations
- Non-tech resources needed
- Med workstation characterized
- Data storage and processing defined
- Mission characteristics (crew size, duration)



- Pilot project performed practice assessment of 2 options for FY18
- Tied together multiple tools to produce cohesive assessment

Collaboration among tools

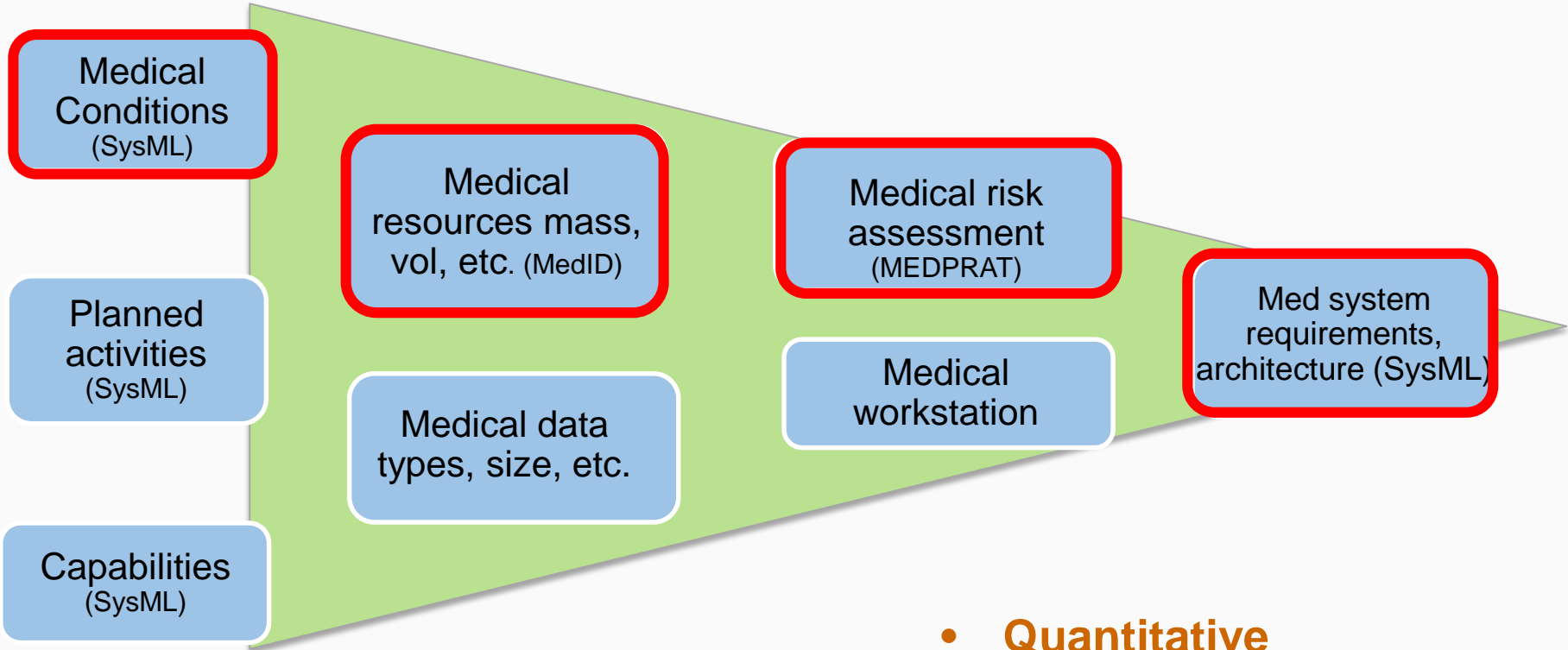


ConOps and discipline info

Resource characterizations


Risk and Hab models

Integrated system and requirements



- Trade Option Characterization**
- 1) Med conditions addressed
 - 2) Standards and rqmts met
 - 3) Master equipment list generated
 - 4) Risk evaluations
 - 5) Non-tech resources needed
 - 6) Med workstation characterized
 - 7) Data storage and processing defined

- **Quantitative**
- **Systematic**
- **Repeatable**

 *Part of FY18 pilot project with representative info to establish tool interfaces*

Produced consistent, integrated data



Sample system comparison summary table produced using multiple tools in collaboration

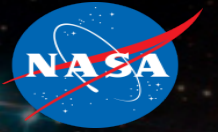
System Characteristic	System 1	System 2
Mass (kg)		115.0
Prob of Loss of Crew		0.0004
Prob of EVAC		0.005
Crew Health Index		0.975
Requirements not met	0	3
Conditions not addressed	0	10

Representative data from tool suite practice runs demonstrating tool interactions to produce cohesive summary



Sample detail that supports summary info

Analysis Results:	Trial A Run1	Trial A Run 2
1. Number of impacted medical conditions	0	10
Trial A Run 1 Impacted Conditions:		
Trial A Run 2 Impacted Conditions:		
Acute Cholecystitis/Biliary Colic		
Acute Radiation Syndrome		
Altitude Sickness		
Appendicitis		
Barotrauma (ear/sinus block)		
Gastroenteritis		
Head Injury		
Indigestion		
Nephrolithiasis		
Space Motion Sickness (space adaptation)		



In summary, ExMC has:

- Established a Systems Engineering team, processes, and products to integrate with exploration programs
- Built a bridge across medical and engineering domains
- Created a capability to provide traceable, defensible system development products



Backup

Why a New Paradigm for Exploration Medical?



- Crew health and performance (CHP) will have significantly greater impacts on mission risk than current operations have
- Deep space exploration missions present new challenges to crew health and performance:
 - Effects of hazards on crew health and performance are not completely known for long durations or deep space
 - Communication delays, blackout periods
 - No resupply, repositioning at best
 - No medical evacuation
- Gateway provides an opportunity to prepare for deeper exploration
- Limited flight resources (e.g., mass, power, volume, data) → view CHP as **an integrated part of flight system development**
- → We are applying systems engineering within HRP to better integrate with exploration offices that are in formulation

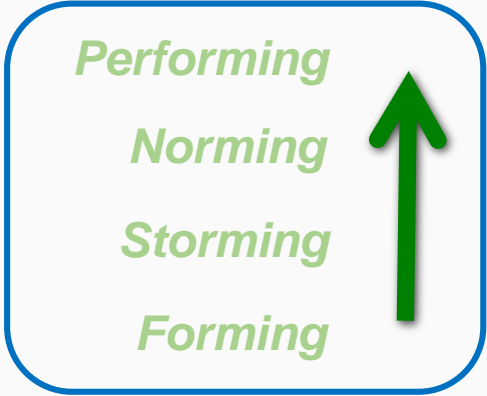


Deep space will be different...

ExMC Systems Engineering – Accomplishments since last IWS



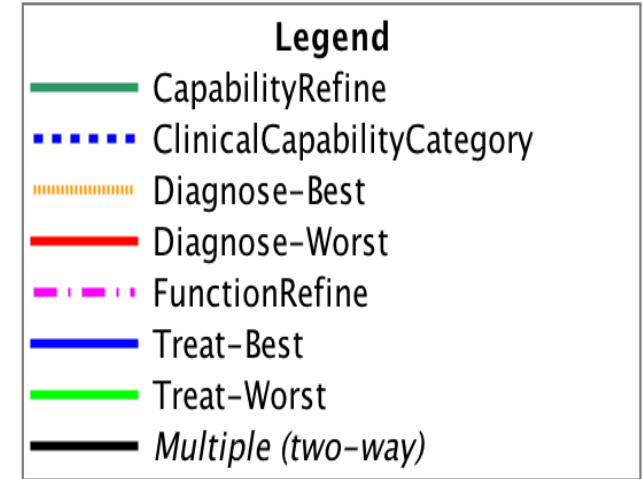
- **Medical System Functional Requirements (HRP OMB milestone)**
 - Completed Recommended Draft Medical System Functional Requirements for Gateway
 - ✓ **Provides foundation for integration with exploration missions**
 - ✓ **Bridged clinical and engineering communities!!**
- **Concepts of Operations**
 - Completed Level 4 Recommended Medical System Concept of Operations for Gateway
 - Completed Level 2 Human Systems Integration Concept of Operations for Gateway
 - Completed first draft of Level 4 Crew Health and Performance System Concept of Operations for Gateway
 - ✓ **Provides system vision, architecture, scenario content informing requirements**
- **Crew Health and Performance System for Gateway**
 - Recommendation agreed among HRP, Human Health & Performance Directorate, and Health & Medical Tech Authority
 - ✓ **Enables integrated system to prevent stove-piped solutions**
- **Trade Study Tools Pilot Project**
 - Met success criteria – produced output of system characteristics coordinated among MEDPRAT, MedID, and SysML model
 - ✓ **Allows quantitative, repeatable, self-consistent analyses of system options**
- **Historical requirements analysis initiated – informed requirements**
 - 3001, ISS PRVD, ISS MORD
 - ✓ **Establishes capability to compare to past systems and build on lessons learned**
- **Applying MBSE**
 - Model maturity increased – trace products created to inform requirements development
 - ✓ **Applies the power of relationships in our model**
- **Other** – Well attended IWS 2018, MBSE training, MBSE community participation (NASA-wide and Centers), IEEE 2019 conference paper



This scenario shows that the medical system can:

- a) Prompt and facilitate data collection for unplanned medical events.
- b) Receive data entry from the patient about the patient.
- c) Provide limited decision support for self-care conditions.
- d) Assess known inventory and report stowage locations to crew via the Gateway Habitat Medical System interface.
- e) Automatically report inventory status to the Ground Medical System.
- f) Generate alerts for the Ground Medical System based upon inflight interactions with the system.
- g) Record and transmit medically oriented, attributable information to ground clinicians.
- h) Retrieve reports in the Ground System that can be reviewed by the Gateway Habitat Medical System

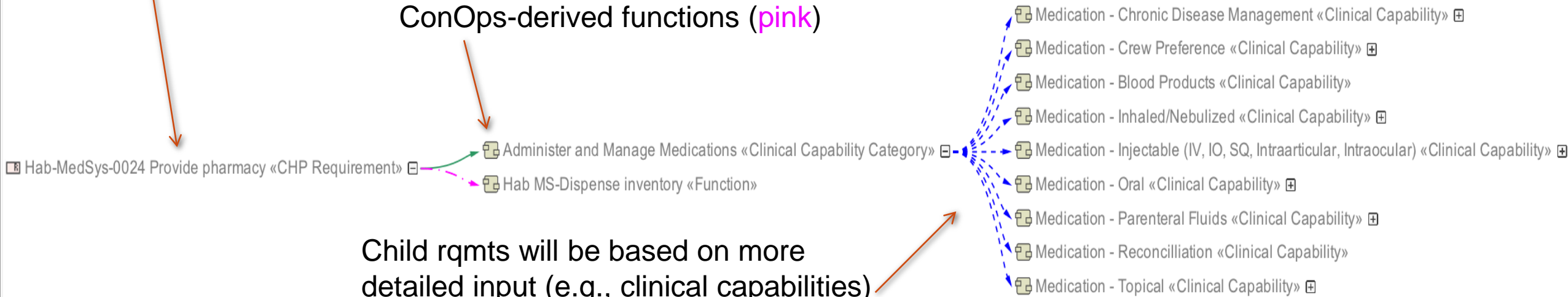
Visualizing the requirement “legs to stand on”



Level 4 rqmt name

Rationale support by clinical capability category (green) inputs and ConOps-derived functions (pink)

Child rqmts will be based on more detailed input (e.g., clinical capabilities) (blue)

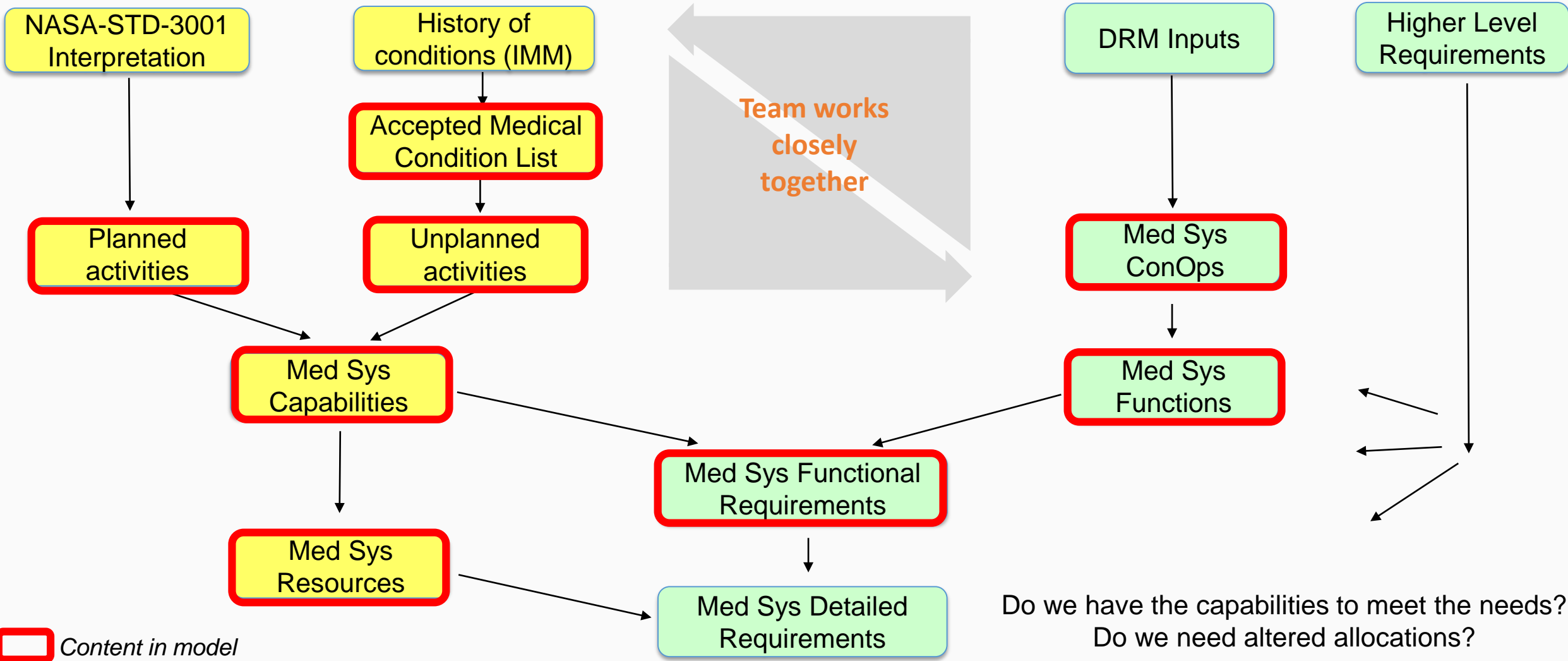


Team activities to get to requirements

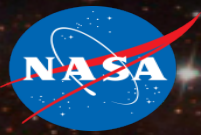


Clinical Domain Activities

Sys Eng Activities



Approach to Get There



Stakeholder needs, goals

NASA Standards

Program requirements & architecture

System functions & behaviors

System requirements & architecture

Subsystem requirements & architecture

Characterize system

Analyze & trade

Design & Build

Began with Mars transit to develop body of work and used that infrastructure for Gateway-relevant content in FY18 and now FY19.

NASA/TM-2017-21930



Interpretation of NASA-STD-3001 Levels of Care for Exploration Medical System Development

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EBR/SC/16
Human Health & Performance Contract
Michelle Urbina
ExMC Medical System Concept of Operations Project Manager
MEI Technologies
Human Health & Performance Contract
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ExMC Clinician
University of Texas Medical Branch
Human Health & Performance Contract
Erin Antonson, MD, PhD

Medical System Concept of Operations for Mars Exploration Missions

Exploration Medical Capability (ExMC) Element
Human Research Program

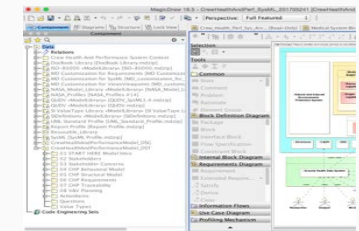
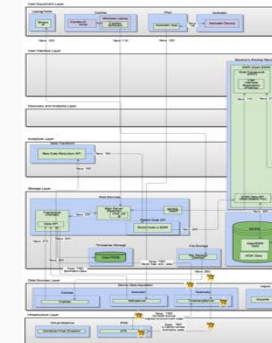
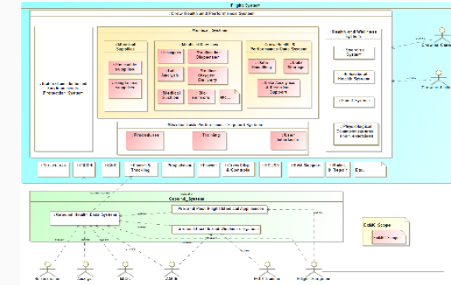
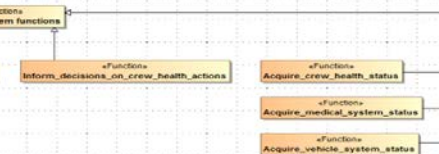
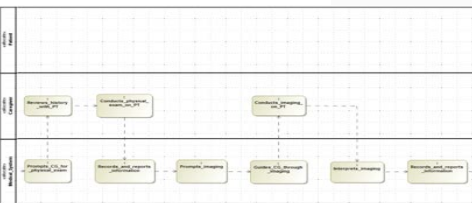
Verify that this is the correct version before use.

Pre-Baseline
February 2017



National Aeronautics and Space Administration
Lyndon B. Johnson Space Center
Houston, Texas

Pre-baseline version. This system is based on the current version. Please verify before use.

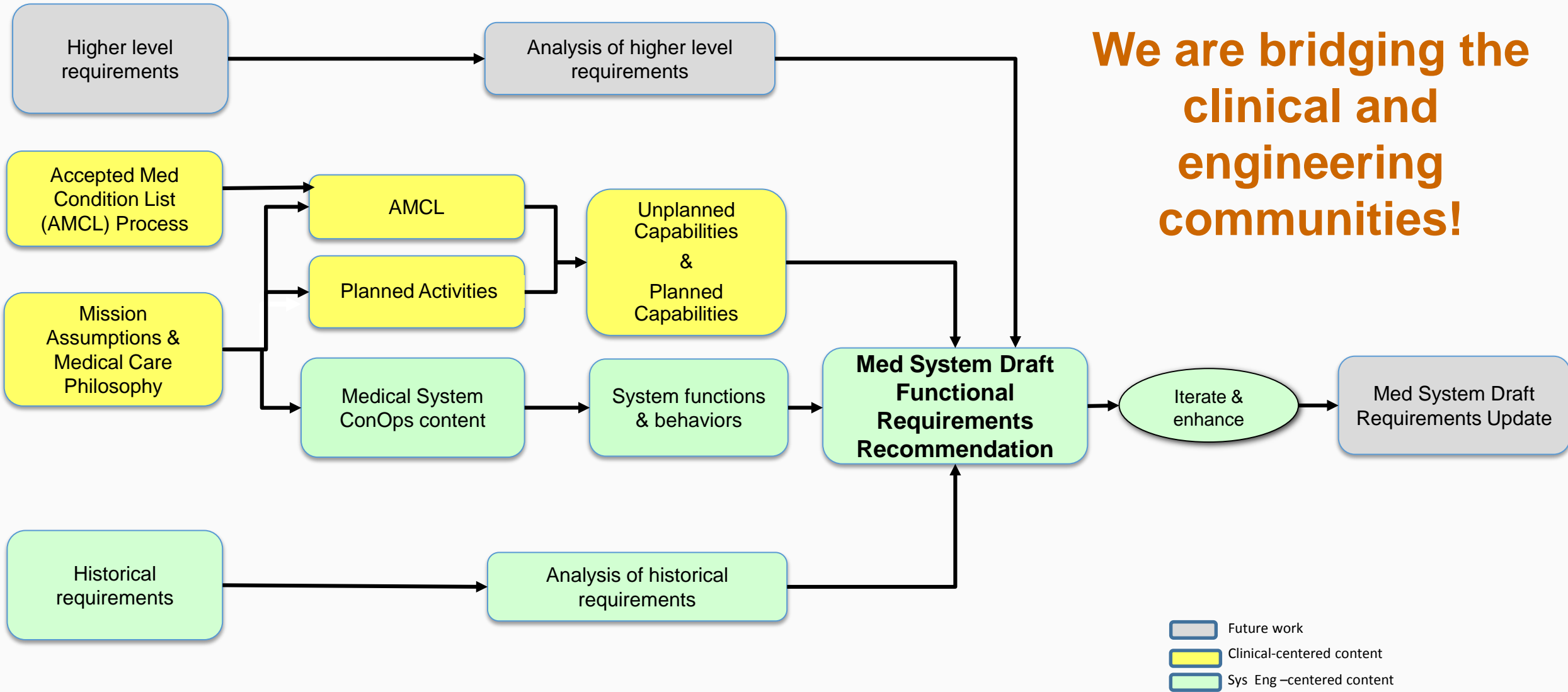
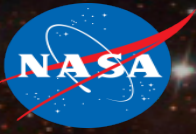


Using Model-Based Systems Engineering:

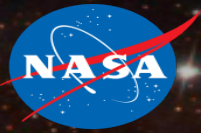
The needs identified by this work will drive future ExMC research

Do we have the capabilities to meet the needs?
Do we need altered allocations?

Team activities

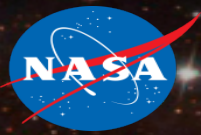


Requirement Examples

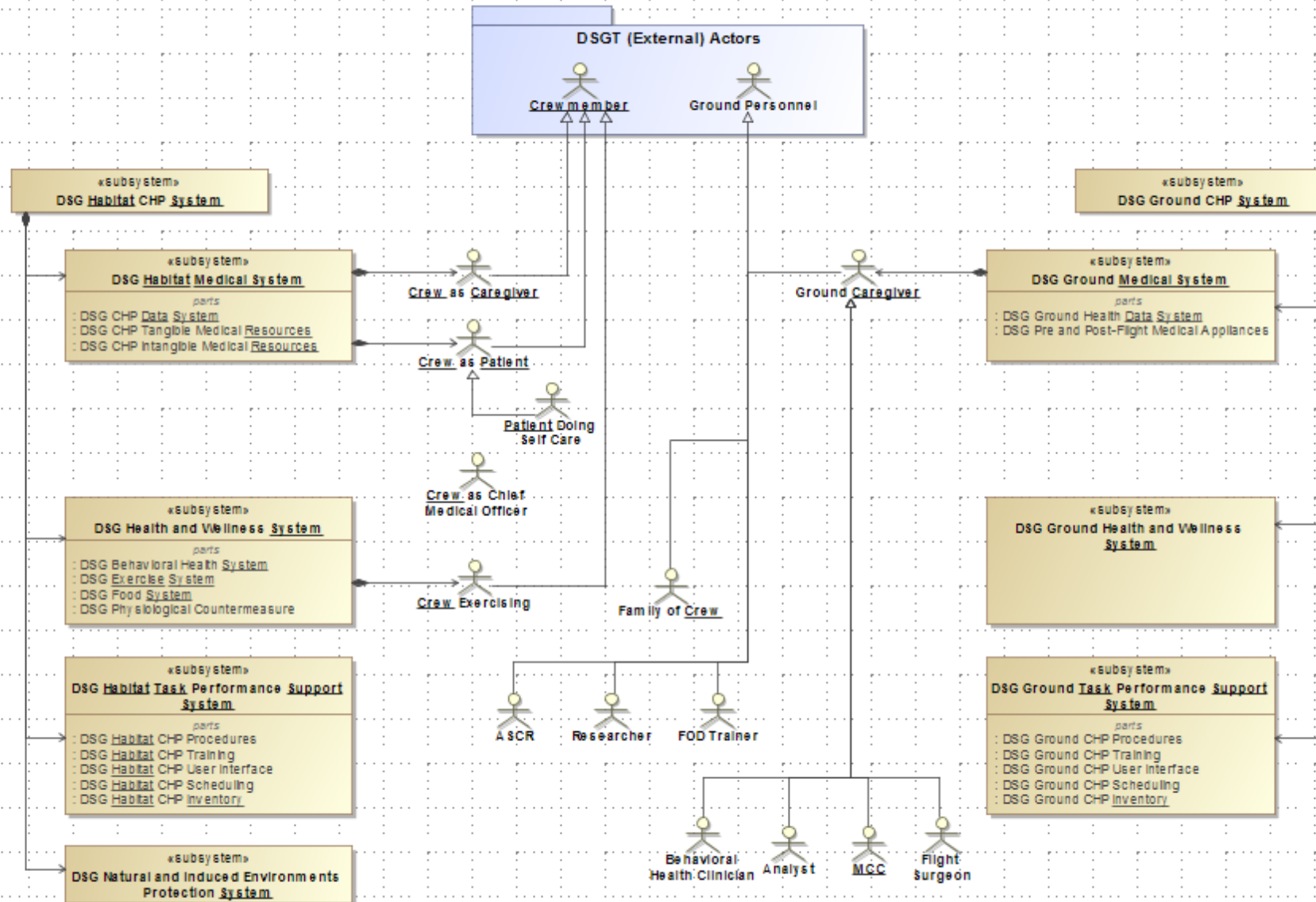


ID	Name	Text	Rationale
Hab-MedSys-0024	Provide pharmacy	The Habitat Medical System shall provide an in-flight pharmacy to the crew members.	Pharmaceutical intervention and prevention, as provided by the in-flight pharmacy, is an essential component of risk management planning for crew healthcare during spaceflight. This includes prepare, administer, document, monitoring, inventory, analyze efficacy of med, titrate, or choose new medication if needed. Pharmaceuticals assist crewmembers with adaptation to the spaceflight environment as well as help manage unexpected medical events that could occur, such as illness or injury. Types of medications needed are specified at Level 5.
Hab-MedSys-0005	Track medical inventory	The Habitat Medical System shall track medical inventory.	Ensure that medical inventory (supplies, equipment, and medications) is tracked at all times including when inventory is dispensed. Specific medical inventories, including quantities, availability, track history, etc., are specified at Level 5.
Hab-MedSys-0204	Perform genitourinary procedures	The Habitat Medical System shall enable caregivers to perform genitourinary procedures.	The medical system needs to provide capabilities (e.g., tools, technology, skills, medications) to perform genitourinary (GU) procedures (such as decompression of bladder). These procedures are needed for treatment of conditions such as urinary retention. Types of GU procedures are specified at Level 5.

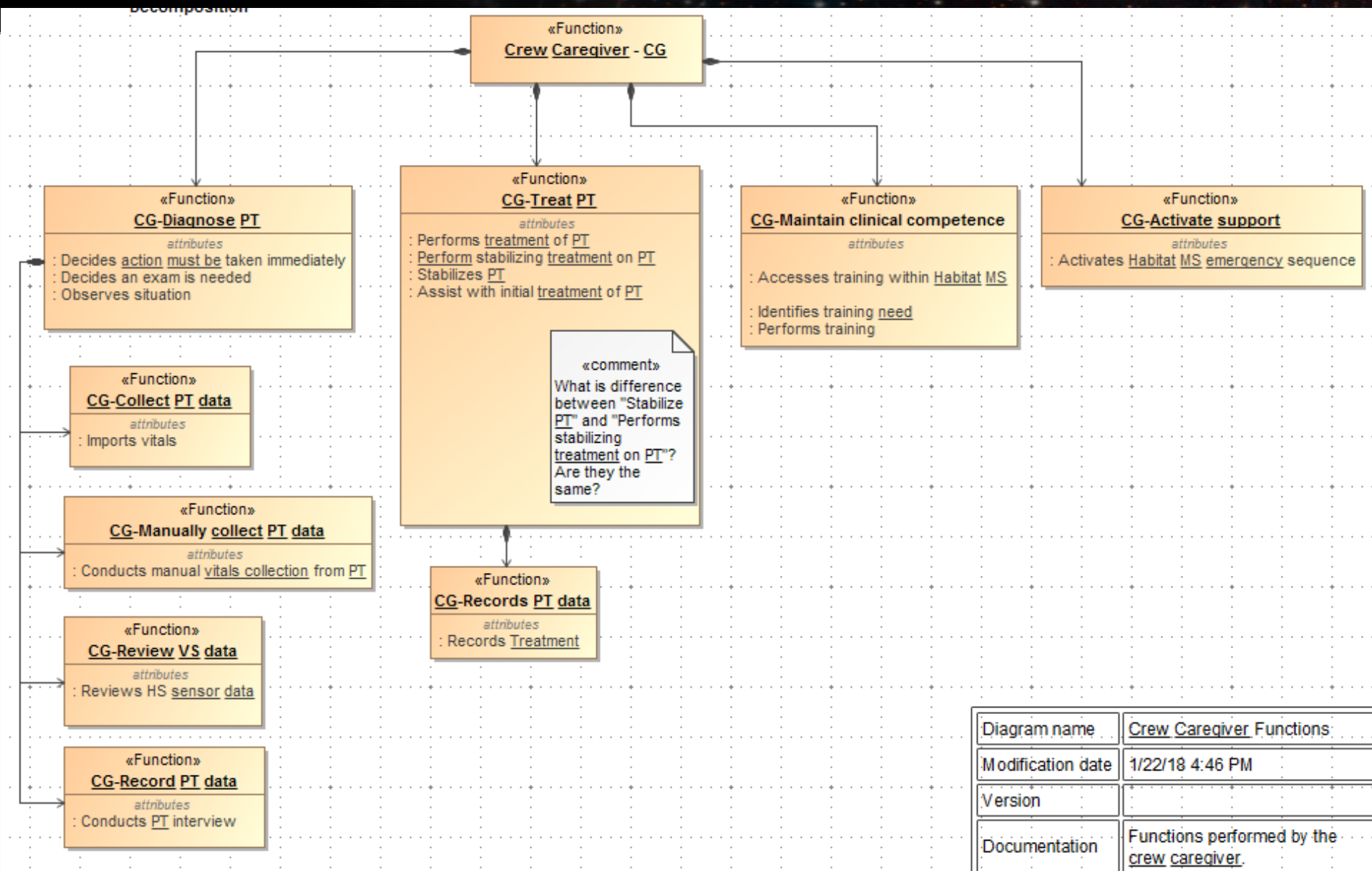
Actors



bdd.[Package] 04_01 DSG CHP Actors [Actors]



Crew Caregiver Functions



MBSE – capture relationships to past Programs



Legend		ISS MORD Requirement [Historical Requirement]											
HistoricalTrace		ISS MORD_5.2.5.2_ISS MORD 5.2.5.2_EXTRAVEHICULAR ACT...	ISS MORD_5.2.8_ISS MORD 5.2.8_PERIODIC FITNESS EVALU...	ISS MORD_5.2.9_ISS MORD 5.2.9_PRELANDING MEDICAL EVA...	ISS MORD_6.3.5.2_ISS MORD 6.3.5.2_BASIC LIFE SUPPORT...	ISS MORD_6.3.5.7_ISS MORD 6.3.5.7_DENTAL CARE	ISS MORD_6.3.6_ISS MORD 6.3.6_IN-FLIGHT BIOMEDICAL MC...	ISS MORD_6.3.7_ISS MORD 6.3.7_TELEMEDICINE CAPABILITY...	ISS MORD_7.5.1.2_ISS MORD 7.5.1.2_AS LOW AS REASONAE	ISS MORD_7.5.8_ISS MORD 7.5.8_EXPOSURE MANAGEMENT F...	ISS MORD_7.7.2.2_ISS MORD 7.7.2.2_NOISE EXPOSURE LEVE	ISS MORD_7.7.4.1_ISS MORD 7.7.4.1_HEARING PROTECTION-	ISS MORD_8.5.3.1.2_ISS MORD 8.5.3.1.2_NUTRITIONAL STA-
Requirements for Analysis [Trace Products]	2	1	1	4	1	7	2	1	1	1	1	1	1
Hab-MedSys-0018 Perform physical exam	2	→	→										
Hab-MedSys-0020 Collect vital signs	1					→							
Hab-MedSys-0021 Monitor vital signs	1					→							
Hab-MedSys-0022 Record vital signs	1					→							
Hab-MedSys-0023 Store vital signs	1					→							
Hab-MedSys-0025 Perform Imaging	2					→	→						
Hab-MedSys-0028 Manage physiological samples	1					→							
Hab-MedSys-0030 Perform airway procedures	1			→									
Hab-MedSys-0032 Perform breathing procedures	1			→									
Hab-MedSys-0033 Perform circulation procedures	1			→									
Hab-MedSys-0034 Perform dental procedures	1			→	→								
Hab-MedSys-0037 Perform immobilization procedures	1			→									
Hab-MedSys-0040 Provide acoustics protection	2								→		→	→	
Hab-MedSys-0044 Provide skin protection	2								→	→			
Hab-MedSys-0050 Assess crew nutritional status	1												→
Hab-MedSys-0054 Assess Behavioral Health	1					→							

Current rqmts in development



Historical rqmts



Are we missing anything in our new set that we've had in the past?

MBSE – Pulling Systems Engineering Work Together

