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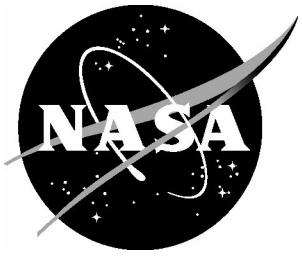

Exploration Medical Capability IMPACT Medical Database – Medical Item Database (MedID) Content Development Methods

Renee C. Lake and Angela R. Harrivel
Langley Research Center, Hampton, Virginia

John F. Reichard
Johnson Space Center, Houston, Texas

May 2023

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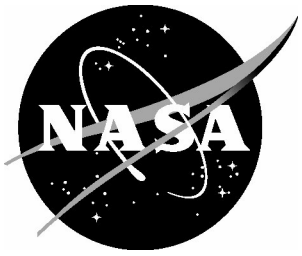

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National Aeronautics and
Space Administration

Langley Research Center
Hampton, Virginia 23681-2199

May 2023

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This work was performed for the benefit of the Exploration Medical Capability (ExMC) Element of NASA's Human Research Program, within the Space Operations Mission Directorate (SOMD). The content of this document was formally reviewed, approved and concurred by project personnel; approved through formal ExMC Control Board review May 24, 2022; and is as-baselined on July 12, 2022 and as-signed December 13, 2022 as IMPACT-PRO-0027 with the same title as this TM for the Informing Mission Planning via Analysis of Complex Tradespaces (IMPACT) Project under ExMC. It is subject to revision. Any end users requiring up-to-date details should get the most-recently-released document from the Project via ExMC.

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INTRODUCTION

The Informing Mission Planning via Analysis of Complex Tradespaces (IMPACT) project encompasses a suite of computational tools that are used to inform systematic trade study evaluations and research prioritizations regarding the optimization of spaceflight medical systems, including the provision of risk assessment metrics, for a given design reference mission (DRM). The IMPACT Medical Database (IMPACT-MD) is the component that virtually houses the clinical and engineering data for medical conditions, capabilities, and resources used to support these analyses. In addition, IMPACT-MD also provides data to the associated SysML model to support the Level 2, Level 3, and Level 4 requirements development needed for IMPACT. IMPACT-MD contains an internal Evidence Library (EL) sub-component that hosts the clinical evidence, treatment and outcome metric data, and incidence data for each medical condition identified for exploration-class missions. Furthermore, a separate Medical Item Database (MedID) sub-component hosts the engineering data and physical attributes (e.g., mass, volume, power, etc.) associated with each medical resource item identified to address the requisite medical conditions.

The IMPACT project is conducted under the Exploration Medical Capability (ExMC) element of the Human Research Program (HRP) within NASA's Space Operations Mission Directorate (SOMD). The reader is referred to the documents in Appendix A for a more complete overview of the IMPACT tool suite and functionality as well as further detail on any associated aspects of the project.

Purpose

The primary purpose of this document is to describe the methods utilized in the collection and verification of engineering data content during the project development phase for the MedID sub-component of the IMPACT-MD project. Engineering content data (both existing and new/future) will be stored in IMPACT-MD for use by the IMPACT project.

Scope

This document will detail the content development and data credibility for the engineering data housed within the MedID subcomponent of IMPACT-MD, which is used to inform the IMPACT 1.0 project deliverables.

Responsibility and Change Authority

This document is under Configuration Management control of the Exploration Medical Capability Element Control Board (ExMCCB). Changes to this document will result in the issuance of change pages or a full re-issue of the document.

IMPACT MEDICAL DATABASE (IMPACT-MD) OVERVIEW

The IMPACT-MD serves as the primary virtual repository used to store, manage, and provide the clinical evidence and engineering resource data that is used to inform trade space analyses for exploration-class mission that are conducted within the IMPACT tool suite, as well as provides

content to the SysML model (used to inform IMPACT-MD requirements), in accordance with procedures outlined in the IMPACT Requirements (IMPACT-REQ-0007) and IMPACT-MD ConOps (IMPACT-CONOPS-0032) documents. Collectively, and as described in the Introduction, IMPACT-MD contains two sub-components: the Evidence Library (EL)_for clinical evidence, and the Medical Item Database (MedID) for engineering data regarding associated resource items, as shown in Figure 1 below. Through the merger of these two data sources, IMPACT-MD represents a single "source of truth" for the IMPACT tool suite for both medical evidence and medical resource engineering data. While IMPACT-MD merges EL and MedID at the data level, two separate user interfaces are maintained for managing the information from a clinical user perspective or an engineering user perspective, respectively, as described in the Medical Database Project Plan.

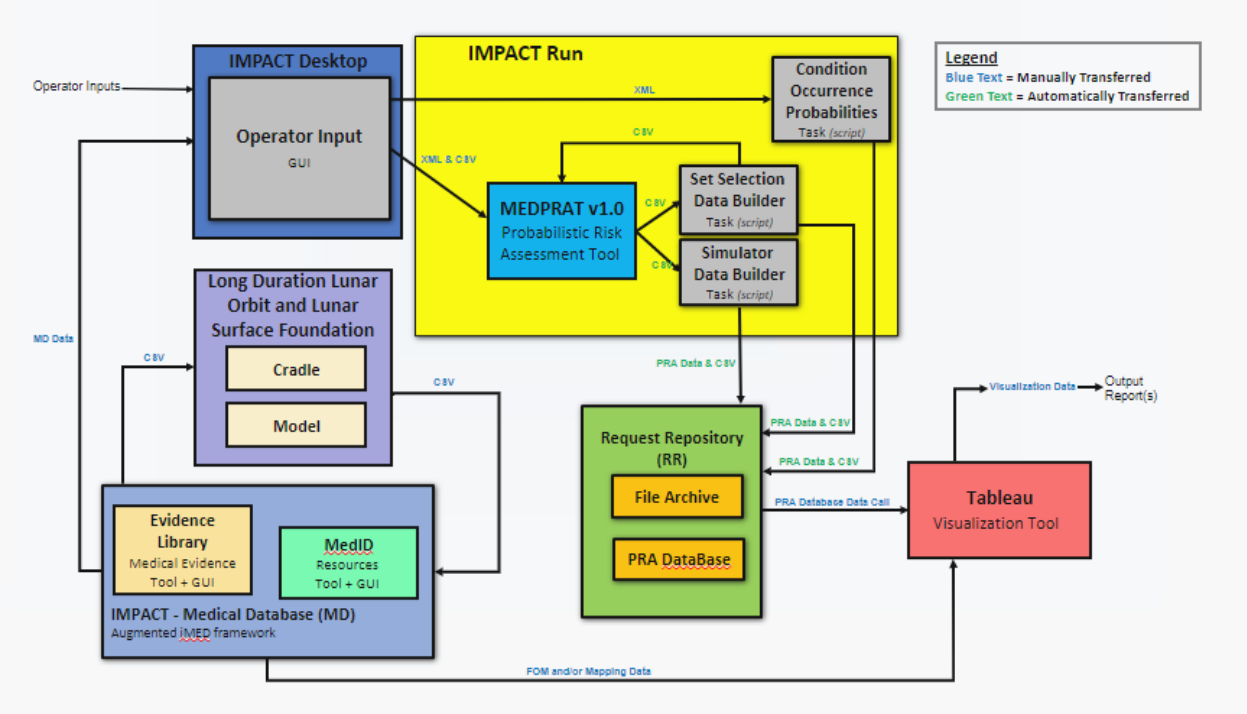


Figure 1 – IMPACT Integration Diagram

The MedID team will deliver:

1. An updated master resource list of medical and pharmaceutical resource items and data to quantitatively inform the identified medical conditions, capabilities, and resources applicable to exploration-class spaceflight missions as specified by the EL data collections effort (for further detail on the EL data collections effort, please refer to the EL Methods paper, HRP-48036).

2. An updated and accurate database of quantitative engineering data that describe physical and other attributes associated with the resources (including quantitative values for mass, volume, power, etc.), as well as descriptive metrics including Figures of Merit (FOMs)

related to the operational environment of a resource item, populated in a validated, traceable manner according to the NASA-STD-7009A (STANDARDS FOR MODELS AND SIMULATIONS) VERSION A w/CHANGE 1 document. The aforementioned document serves as the technical standard that "establishes uniform practices in modeling and simulation to ensure essential requirements are applied to their design, development, and use, while ensuring acceptance criteria are defined by the program/project and approved by the responsible Technical Authority." (Standard for Models and Simulations | Standards (nasa.gov))

3. Worksheet template(s) to help guide the data survey and collection effort for all resource engineering data.

MedID Overview

The MedID sub-component of IMPACT-MD represents a reviewed and verified virtual repository of engineering data and associated information for specific medical resource items that are used in support of the IMPACT project to inform research prioritizations and systematic trade study evaluations for exploration-class spaceflight missions. The objective of MedID is to accurately capture medical resource item physical and quantifiable properties and additional data attributes in support of spaceflight medical system evaluation(s). MedID is the user interface for approved users (with roles outlined in Table 1) to view, enter, and modify the engineering data, FOMs, and other attributes regarding the medical and pharmaceutical resource items within IMPACT-MD. Output from MedID/IMPACT-MD informs the following components within the IMPACT tool suite:

- Medical Extensible Dynamic Probabilistic Risk Assessment Tool (MEDPRAT) – the Monte Carlo-based computational engine that IMPACT uses to perform human health and medical risk predictions, which is extensible to a variety of exploration missions. The set selector within MEDPRAT allows for the determination of the most optimal medical set required to minimize user-weighted risk factors such as Loss of Crew Life (LOCL), Return to Definitive Care (RTDC), etc., within pre-determined user centric constraints, such as mass, volume, etc.
- Request Repository (RR) – SQL-based secure database that keeps track of the input and output files generated for the requested IMPACT studies, also provides the data for post-processing visualization.
- Medical System Foundation Model – the model-based systems engineering (MBSE) component that maps medical systems requirements to capabilities and allows selection of specific resource items (via MedID). Provides assistance in producing reports on how a particular choice within a medical set or kit impacts the Chief Medical Officer's (CMO) ability to optimally manage medical conditions or meet crew/mission specific requirements.

Engineering Data Overview

Prior to the merging of EL and MedID to create 'Medical Database', MedID had traditionally existed as a standalone database of characterized medical resource items. Initial resource content for populating the original legacy version of MedID largely originated from the Crew Health & Safety (CHS) Integrated Medical Evidence Database (iMED). iMED is an existing database of information

cataloging medical and pharmaceutical resource items flown on the International Space Station (ISS), providing informed estimates of parameters such as mass and volume. These estimates are informed by and collected from NASA space and exploration medicine clinician and biomedical subject matter experts (SMEs). Further augmentation of MedID content evolved under the IMPACT project to the inclusion of additional resource items derived from ExMC Medical System Foundation for Level of Care IV Short Duration Lunar Orbit V 1.0 [1-3]. More information on the iMED architecture can be found in the IMM Conceptual Model Document (HRP-47077).

Engineering data stored in MedID serve as the source of "engineering truth" for the IMPACT tool suite regarding quantitative and/or other physical attribute information (e.g., mass, volume, power, etc.). MedID associated medical and pharmaceutical resource items are stored within the database as well, providing specific information that supports Level 2, Level 3, and Level 4 requirements stored in the SysML model. Within the database, resource items are described or cataloged consistent with the naming convention for the resource items as they exist within the Capability Resource Table (CRT) listings as provided by the Clinical and Science Team (CST).

As described in the EL Methods paper, the CRT "contains a list of the capabilities needed to prevent, diagnose, provide acute care, and provide long-term management for the specified medical condition. Each listed capability is then linked to the resources needed to provide that capability, and each resource is linked to alternatives that may be substituted should the primary resource be unavailable. In this way, medical risk "buy-down" can be translated into the discrete mass, power, and volume estimates needed to inform engineering trade space analysis." Given that each MedID resource item is derived from the corresponding EL resource via the CRT, the adoption of the consistent naming convention ensures compatibility with existing EL documents and designations, and thus eliminates the need for any resource name translation between EL and MedID. Resource items are thus displayed and can be searched upon within the MedID user interface using the same name/label as they are referenced within the analogous EL-based user interface within MD.

The MedID user interface functions as an entry point into this 'virtual warehouse' of medical resource items, within which engineering and other descriptive data are stored and indicated for each resource item according to the following relatable attribute areas (as depicted in Figure 2): Details, Measurements, Power Information, Pharmaceutical Information, Mission Information, Operational Environment, and Source. These FOMs are properties/metrics used to characterize the resource item in terms of its performance, operational environment requirements and impacts (such as sensitivity to acoustic noise or the production of waste or interference), technology readiness level (TRL), data architecture requirements and specifications, and other system status information (further detail is found in Appendix B). Note that these data attribute areas share overlap and similarity for both pharmaceutical and medical resources, with the exception of Power Information and Pharmaceutical Information, which are mutually exclusive (i.e., Power Information is not relevant for pharmaceutical items, and Pharmaceutical Information is not relevant for non-pharmaceutical items).

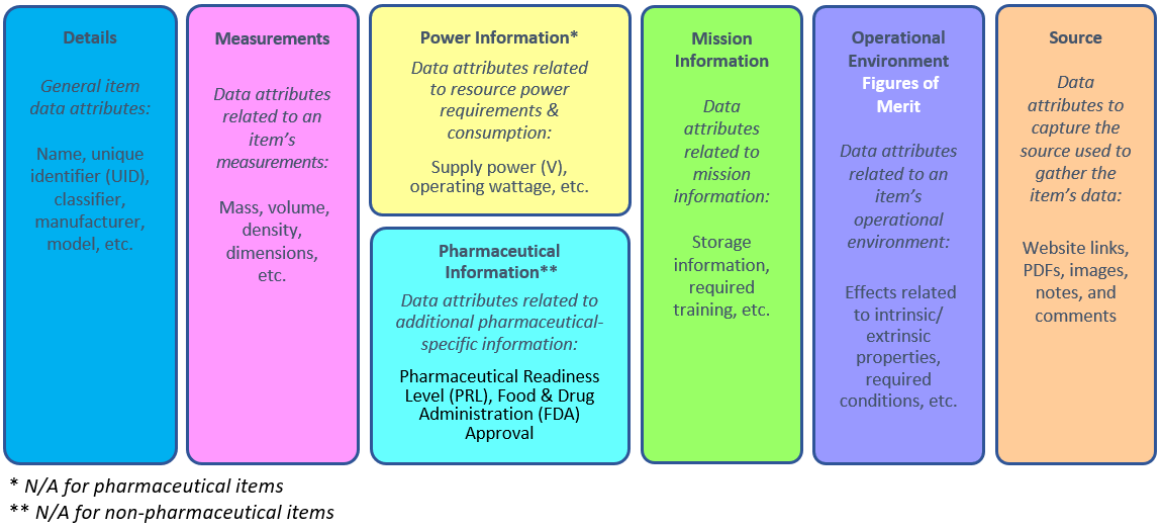


Figure 2 – MedID Relatable Attribute Areas

Examples of the engineering data attributes and associated information for medical and pharmaceutical resource items as displayed within MedID are shown in Figures 3-4 below. Figure 3 depicts the layout of the General Details and Measurements pages for the 'Wound Care - Adhesive Dressing (Steri-Strips)' resource item (note: pages are depicted in a tiled manner for display efficiency in this document). Figure 4 depicts the current Operational Environments page layout, using a Pharmaceutical resource (Oxymetazoline 0.05% 1 Spray) to show how the Operational Environment parameter and any corresponding FOMs are indicated for the item.

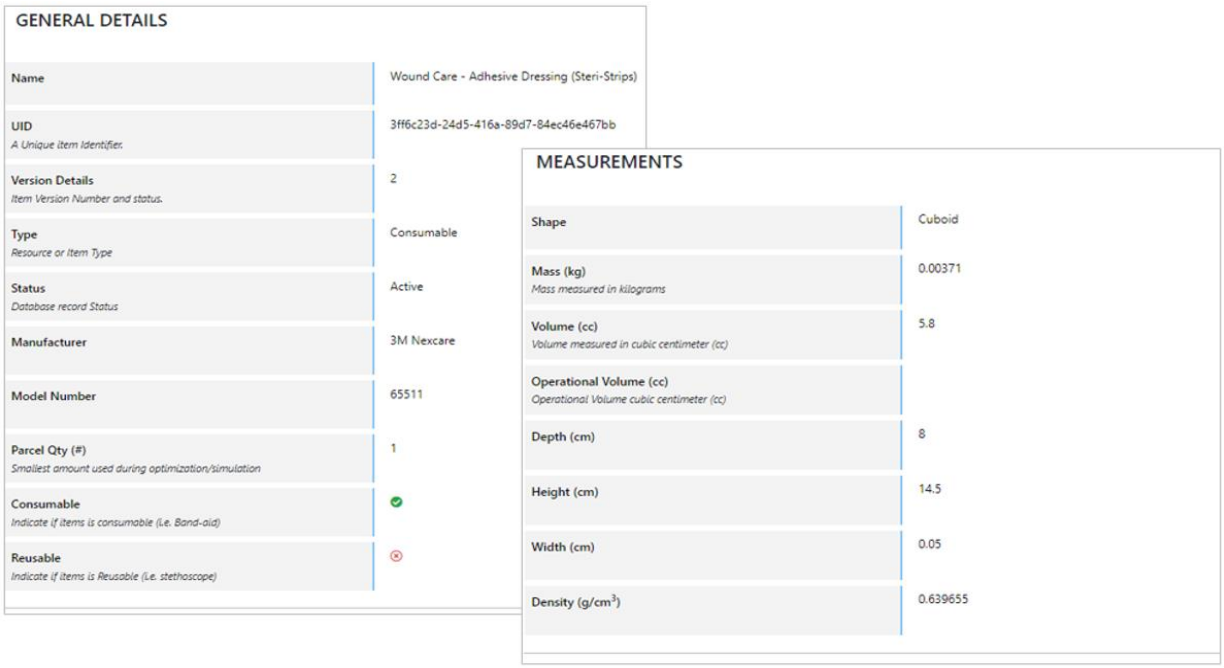


Figure 3 – General Details and Measurements for medical resource item (Wound Care - Adhesive Dressing (Steri-Strips))

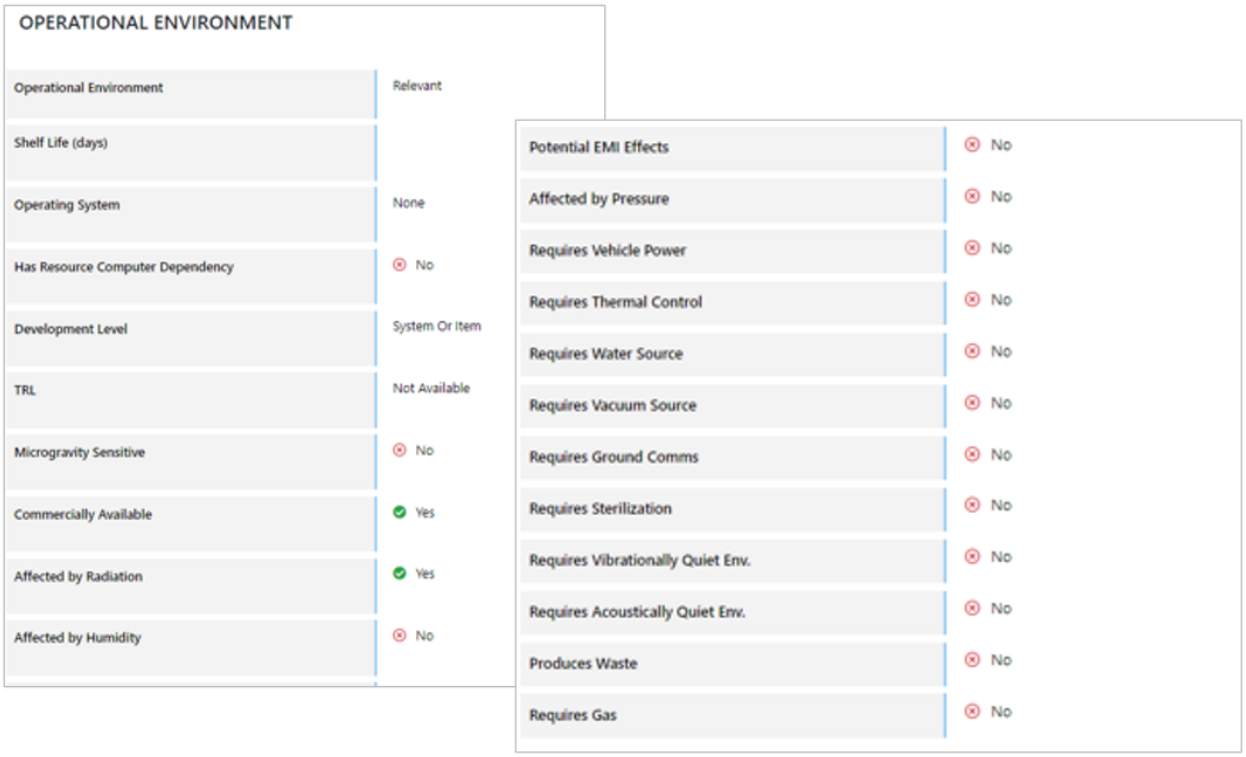


Figure 4 – Operational Environment parameters and FOMs for pharmaceutical item (Oxymetazoline 0.05% 1 Spray)

Engineering Data Update Overview

As mentioned previously, MedID had traditionally existed as a standalone database of characterized medical resource items prior to the merger to form IMPACT-MD. Resource data attributes and FOM content for those existing medical resource items (or a subset of them) were carried over to populate the merged IMPACT-MD database by virtue of an updating process conducted on the legacy dataset. This updating process essentially involved reconciling the existing MedID resource items against the forthcoming medical resources identified by the clinical team during the evidence data collection exercise, with newer items either being added in addition to, or in place of, outdated or otherwise superseded resource items, and archival of legacy resource items that were deemed no longer relevant.

As a focused effort within this reconciliation process, existing data to be retained in the database were subject to a data scrubbing process, defined herein as modification or removal of any data content that was incomplete or inaccurate within the database, with the objective of improving the data's accuracy, completeness, and validity, while conserving as much data content from the original MedID content as is feasible and/or relevant to avoid reduplication efforts. In this way, the MedID master resource list was fully updated in its entirety and imported into the IMPACT-MD by the Lead Programmer and Lead Content Developer after the end of the evidence collection process (initial MedID content population was completed December 2021). The full update

produced a master list of medical and pharmaceutical resource items and data that are (to the greatest extent possible) updated, verified, and relevant in informing quantitative metrics for exploration-class missions, per the data credibility assessment described in section 4.

ENGINEERING DATA METHODS

Content Development Overview

The medical resource data content resident within the MedID sub-component of IMPACT-MD will be collected and vetted by the ExMC IMPACT-MD team in a peer-reviewed and configuration managed method as described within this document and in compliance with NASA-STD-7009A (STANDARDS FOR MODELS AND SIMULATIONS) VERSION A w/CHANGE 1.

Data Population

Given that medical data and associated guidelines/best practices are likely to evolve with time, driven by advances in medical technology as well as changes in mission requirements, it is envisioned that modifications to the engineering data content for various medical resource items will be necessary over time to maintain a high level of fidelity for the resource item data.

To this end, and to provide and maintain the large volumes of MedID content, a plan was implemented to informally "crowd-source" SMEs/support content custodians within the existing IMPACT-MD team to tap into available databases and data references that are used to source the data. While the Lead Content Developer was designated as the primary or default content custodian, additional volunteers were solicited to also serve as secondary or support content custodians to ensure timely and appropriate coverage for data population efforts, particularly when/where the quantity of incoming new data, as well as requirements for modifications to existing data, demanded additional effort beyond that available for the primary custodian's tasking level. These custodians were responsible for researching and populating specific data attributes and FOMs for a given set of resource items per the Lead Content Developer's assignment/discretion. Given the anticipated special considerations for resources within the Pharmaceutical resource type (due to less availability of sourced quantitative data for mass and volume, as well as unique factors regarding the mandatory inclusion of packaging for liquid and cream-based medications), the Pharmaceutical resources were exclusively tasked to a single custodian with pharmaceutical expertise to maintain consistency in the consideration and disposition of the data elements. A listing of the primary roles and responsibilities as relevant to the MedID construct is shown in Table 1 below.

Table 1 – Roles/Responsibilities Summary

Role	Responsibility (within the context of MedID)
ExMC Clinicians	Provides clinical subject matter expertise, clinical content editing and approval, resource mapping, and peer review (including engineering data inputs for clinical resources).
ExMC Pharmacists	Provides pharmaceutical subject matter expertise, pharmaceutical content editing and approval (including pharmaceutical data inputs).

MedID Lead Content Developer	Provides engineering subject matter expertise. Verifies data and sourcing, populates resource engineering data, attributes, and Figures of Merit (FOMs) in MedID. Is the default content custodian for MedID.
Support Content Custodians	Assists with the population of resource engineering data, attributes, and Figures of Merit (FOMs) in MedID to assist and support Lead Content Developer.
MedID Lead Programmer	Develops the Medical Database software, data handling, user interfaces, and software interfaces. May also populate resource item content.
Support Programmer(s)	Assists with developing the Medical Database software, data handling, user interfaces, and software interfaces.

Data were collected and recorded by each custodian in a templated Excel spreadsheet format to permit complete cataloging and traceability from source material to data and from data to resource names within the master resource list. A draft version of the data collection worksheet is presented in Appendix C. The data worksheet is Excel-based, with tabs for each of the following resource types: Consumable, Nonconsumable, Device, Hardware, Pharmaceutical, Resupply, Skill, Software, Supply, and Not Assigned. The worksheet features dropdown boxes for choosing pre-specified content (such as that for resource type, item shape, and true/false designation on various FOMs, etc.). The sheets for all non-pharmaceutical types share essentially identical format and content, while the Pharmaceutical worksheet is inclusive of content relevant to the pharmaceutical genre.

The data custodian caretaking process went into effect after completion of the initial database scrub in April 2021.

4.2.1 Content Population for New Items

As previously mentioned, resource content for the original legacy version of MedID was largely derived from iMED with additional augmentation from NASA space and exploration medicine clinician and biomedical subject matter experts (SMEs) and the ExMC Medical System Foundation for Level of Care IV Short Duration Lunar Orbit V 1.0. Additional content that may be added to MedID (i.e., beyond the current instantiation), such as that incoming from the ongoing EL data collection effort focused on longer-duration missions (Lunar Surface Operations), will be considered 'new' from the perspective of the legacy content.

The general process of inputting new content into MedID (during the project development phase) is detailed as follows and graphically depicted in Figure 5:

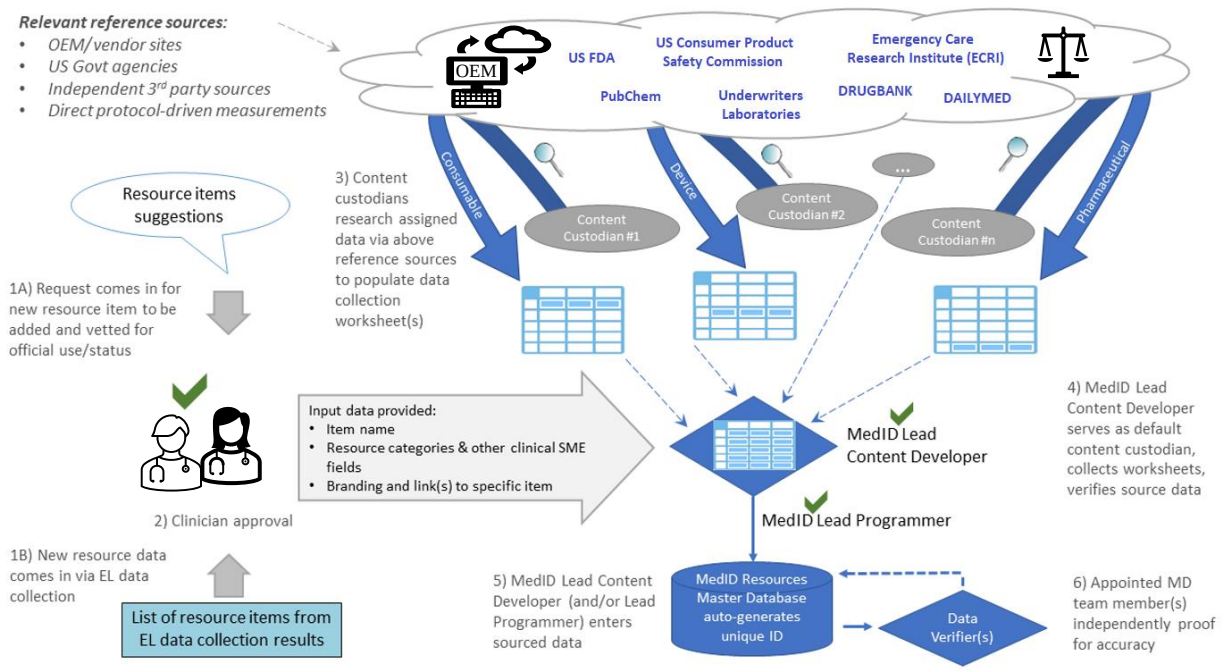


Figure 5 – MedID Content Population Flow

1) Specific items are requested to be placed into MedID to officially support trade study/analysis needs. These requests for new resource items may be solicited via:
   A) an IMPACT-MD user, clinician and/or CST member, or authorized engineering content developer
   B) new resource requirements arising from new evidence (as detailed in the document EL Methods)

2) Clinicians are the intended curators of the medical database inventory by virtue of providing directives as to what resource items are required within IMPACT-MD. Once a request is received, it is then referred to the authorized clinician approvers within the CST for approval, per a list of authorized clinician approvers (planned to be included within the MedID application, tentatively within the Help menu for documentation purposes and straightforward access for the user).

3) Once clinician approval has been acquired, the following information shall be forwarded to the MedID Lead Content Developer: item name, associated resource category (and any other clinician/SME fields), branding/vendor of item (if known/available), and reference links to the specific item requested (if known). The requestor will also consult with the clinician to verify the mapping of the item back to the EL via the CRT.

4) Following clinician approval and forwarding of the baseline data to the MedID Lead Content Developer, the respective content custodian(s) will populate the corresponding data attributes for which they are responsible via researching/consulting the relevant references sources as

detailed in section 3.4 and recording that data within the custodian worksheet(s). Data shall be recorded in default units consistent with section 3.3. Depending upon the number of available data custodians, as well as factors related to queueing of the items (such as timing related to availability/readiness of items from the CRT lists), the Lead Content Developer may assign to individual custodian items within a single specific Resource Type (e.g., Consumables, Devices, etc.) or items encompassing a variety of Resource Types.

5) Once custodian research is complete, the MedID Lead Content Developer (or an appointed alternate selected from Table 1) will collect the worksheets and cross-check/verify the sourced data as recorded in the worksheet via an independent search/audit of the data via the indicated source links. If an error is discovered in the recorded data in the worksheet (as compared to that available from the source), the MedID Lead Content Developer will manually override the original value recorded in the worksheet and annotate the correction per the relevant field within the worksheet.

6) Once this data has been verified, the MedID Lead Programmer (and Lead Content Developer) will import the data into the MedID resources master database (either via an Excel-based mapper file when large quantities of data are desired for import or via manual entry). Subsequently, a globally unique ID will be generated and auto-assigned for each incoming resource item.

7) Once the resource item has been logged into the database and all relevant data fields have been populated, the Lead Content Developer or other appointed MD team members act as data verifiers to independently proof the data for accuracy. This proofing step is accomplished by referencing and verifying the information entered in the custodian worksheets to ensure that no typographical or numerical errors exit within the entered data.

As mentioned above, the Pharmaceutical item research was handled via a single data custodian with pharmaceutical expertise. In general, the workflow for gathering data for pharmaceutical resources was in alignment with the steps outlined in Figure 5. However, some additional steps were undertaken to acquire more specific mass and volume estimates for the pharmaceutical items beyond that generally available via vendor-based or other websites. To this end, a sampling approach was employed to produce associated standard curves using a subset of experimental data as obtained via NASA JSC Pharmacy Operations personnel for representative items which shared mutual overlap between MedID and existing ISS inventory. This approach was deemed necessary because pharmaceutical weights were not available via any known public database or vendor site (to the knowledge of the team and the authors). In addition, the two-dimensional size information for representative tablets and capsules was estimated from images available from NDCList.com, which is the complete repository of National Drug Codes (NDC) Information.

In contrast, thickness (z-axis) information was estimated using a sampling approach that physically measured an arbitrarily-selected set of medications. Standard curves were generated for capsules, tablets (oval and round), injectable solutions, ophthalmic solutions, and topical creams/ointments using available experimental data, and mass and volume for a specific size or amount of drug were interpolated via the standard curve for instances where specific measurements were not available

for an item. Additionally, volumes for glass vials, bottles, and ampules were calculated via published dimensions available from available vial manufacturers (which were assumed to be an appropriate estimate for indicated sizes shipped by the pharmaceutical manufacturer). Further detail on the pharmaceutical sampling approach and data collection is outlined in Appendix D.

4.2.2 Content Population for Existing Items

The general process of modifying existing content in MedID will follow an abbreviated version of the data population flow for new items, given the expected narrower scope of this scenario. Specifically, the scenarios wherein an existing item would be modified are somewhat limited in number since any significant or material changes to the primary data such as vendor, mass, volume, dimensions, etc. would necessarily require a 'new' item to be generated (as well as archival/removal of the superseded item, if applicable). Examples of scenarios in which modifications to existing items would be necessitated include but are not limited to:

- a newly requested FOM being approved and becoming available for the relevant application
- additional information on a resource or set of resources becomes available
- inclusion of new or additional vetted reference sources (e.g., a new pharmaceutical database, Medical Resource Distributor Catalog, or data Application Programming Interface (API)

To this end, the data population process for modifying an existing item will be as follows:

1) Specific items are requested to be modified in MedID via an IMPACT-MD user, clinician and CST member, or authorized engineering content developer.

2) Once a modification request is received, it is then referred to the authorized clinician approvers within the CST for approval. Once clinician approval has been acquired, the requested modified information shall be forwarded to the MedID Lead Content Developer, and the requestor will also consult with the clinician to (re)verify the mapping of the item back to the EL via the CRT.

3) Following clinician approval and forwarding the modified data to the MedID Lead Content Developer, the MedID Lead Content Developer will perform an independent audit of the modified data via the provided source links and annotate the modification in the relevant field within the original worksheet.

4) The MedID Lead programmer (and Lead Content Developer) will enter the modified data into the MedID resources master database.

5) Once the resource item has been logged into the database and all relevant data fields have been populated, the Lead Content Developer or other appointed MD team members act as data verifiers to independently proof the data for accuracy. This proofing step is accomplished by referencing and verifying the information entered in the custodian worksheets to ensure that no typographical or numerical errors exit within the entered data.

4.2.3 Content Population for Resources of Test/Notional Status

Authorized users of IMPACT-MD may desire to add notional or test items to the database to fulfill an analytical or trade study objective without interfering with current or officially vetted resource content. These modifications can be achieved by creating a new resource item with a non-duplicative name concerning any of those currently in the database (and ideally representing notional status, such as 'test medical device 1') and self-population of any desired data fields to support their analyses, including setting the 'Test Status' flag (within Details section of MedID) to 'TRUE' to designate the test/notional status of the resource item. Such notional resource items do not require formal approval or vetting and are thus not subject to the same content population constraints as those items designated for official IMPACT analyses use.

Default Units

Default units for resource items recorded within MedID are specified and documented herein to establish standardization for all relevant variables to ensure interactions between the units are not a problem, as per sections 4.2.2b (General M&S Development Recommendations) and E.4.1.2 (Verification Factor) of NASA-STD-7009A w/ CHANGE 1.

The default engineering units for associated resource items within MedID are shown below in Table 2. Note that while some pharmaceutical items may include English units in their resource name (e.g., Ace bandage 3 inches), the actual engineering dimensions for the item are defined in Metric units (cm). Unless otherwise specified, data will be reported within three significant digits.

Table 2 – Default units for MedID resource items

Parameter	**Unit**
Charge	Amp-hour (Ah)
Current	Ampere (A)
Density	Grams per cubic centimeter (g/cc)
Dimension (length, width, height)	Centimeter (cm)
Dosage (liquid pharmaceutical)	Milligram per milliliter (mg/ml)
Dosage (solid pharmaceutical)	Milligram (mg)
Energy	Kilojoule (kJ)
Input Impedance	Megaohm (MΩ)
Mass	Kilogram (kg)
Power	Watt (W)
Time	Hour (hr)
Voltage	Volt (V)
Volume	Cubic Centimeter (cc) – *equivalent to mL*

MD Resource Data Sources

Engineering data and supporting information (data attributes, FOMs, source links, images, spec sheets, etc.) for resource items will be collected, documented, and verified via the following pre-vetted sources:

- Manufacturer/vendor sources – manufacturer/vendor websites and product literature

- US Government sources – US Government agencies or commissions (US Food and Drug Administration (FDA), Consumer Product Safety Commission, PubChem, etc.)

- Independent third-party sources – Underwriters Laboratories, Emergency Care Research Institute (ECRI – an independent non-profit organization focused on healthcare safety, quality, and cost-effectiveness), etc.

Should alternate sourcing of data in addition to the above be required, a consensus will be sought in consultation with EL and MedID team members and associated experts/SMEs regarding the acceptability of proposed alternate sources. For instances where CRT-specified resource items represent matches with legacy MedID resource items (but where the legacy source link is expired or otherwise not available, i.e., the legacy vendor site no longer sells the item, and the item is available through alternate vendors sites), a source link from an available alternate vendor will be obtained and updated within the database. However, if the resource item is discontinued and cannot be found in alternate sources/vendor sites, the legacy resource item for that specific brand will be archived, and a new resource item (of an alternate brand but similar size and purpose) will be created using updated links or sources.

If necessary data are not available - or are otherwise less than optimal for a particular item via the above sources (such as for those items resulting from post-manufacturer custom modifications as deemed necessary or appropriate by the CST team) - the option of obtaining better estimates for the physical characteristics of an item via direct measurement of the item can be (and presently is) realized. This process is completed via the execution of relevant, documented experimental protocols by qualified NASA or contractor individuals (pharmacists, engineers, clinicians). In these instances, the data acquired via these measures serve as improved estimates for the resource item(s) desired.

It is important to note that neither the U.S. Government nor NASA endorse or recommend any commercial products, processes, or services. Reference to or appearance of any specific commercial products, processes, or services by trade name, trademark, manufacturer, or otherwise, in NASA materials does not constitute or imply its endorsement, recommendation, or favoring by the U.S. Government or NASA, nor does it represent a commitment of Agency resources to that effect. The brands, models, and associated reference links and sources that are referenced within MedID are utilized with the intent of providing realistic and traceable information for the database's research content that can be reasonably assumed to appropriately represent the given resource item (and/or its functionality) as it is described within the EL resource list.

IMPACT-MD Gap Analysis

A gap analysis was performed (August 2020) on the MedID resource contents to identify additional or expanded data attributes and categories that may benefit from new or further detailed definitions or augmented resource items. Data attribute categories were considered regarding their current state, the desired state, the gap or question being identified, and the standard, expected metrics, and corrective action(s) to be taken to meet the desired state. Consideration for a proposed FOM was driven by a specific question or gap in the current knowledge state of the FOM-

associated metric relative to what presently existed (if any) in the database, and priority was given to those data attributes that would serve to improve risk analysis or otherwise facilitate trade study capability for IMPACT v1.0 and beyond. With respect to the 'current state,' for most proposed FOMs, this was captured as: "No indication / does not exist in system" to reflect that no information on that FOM was currently available in the database. The 'desired state' describes the expected status for the proposed FOM once the indicated gaps in information and metrics have been addressed via the indicated 'corrective action,' with an indication of the 'expected metric' (e.g., digit code, data, resource item, or binary Yes/No designation) that would result from successful completion of the analysis and corrective action steps for the FOM.

Overall, multiple FOMs were identified as having potential benefits for providing an increased level of detail for resource items. These new FOMs included coding for training, Knowledge/Skills/Abilities (KSA), other forms of expertise, 7 subcategories of digital data types, and 22 additional FOMs. While the list of attributes and FOMs identified in the gap analysis is not yet included in the current version of MedID (with noted exceptions below), they represent recommendations or candidates for inclusion into MedID at a future date, subject to project prioritization and approval. Two noted exceptions to the statement mentioned above are concerning the KSA FOM. The IMPACT project has tentatively earmarked the KSA FOM for version 2.0.

Additionally, a suggestion was incorporated regarding including a FOM to indicate the type of operating system (O/S) for any software-driven devices (a request which was received and approved via IMPACT SRR reviewer comment disposition). Although the O/S FOM could be considered a subtype within the 'digital device types' designation within the gap analysis, it was not explicitly detailed within the August 2020 gap analysis (and thus does not explicitly appear in the Appendix F listing). However, under the IMPACT SRR comment disposition consideration, the O/S FOM was selected for imminent implementation into MedID. Therefore, further detail on the gap analysis results can be found in Appendix F.

ENGINEERING DATA CREDIBILITY

As per NASA-STD-7009A w/CHANGE 1, the definition of credibility (as it relates to data) is described as the quality to elicit belief or trust in the Modeling and Simulation (M&S) results, with the assessment of data credibility being predicated upon the assessment of eight objective factors: Data Pedigree, Verification, Validation, Input Pedigree, Uncertainty Characterization, Results Robustness, M&S History, and M&S Process/Product Management. Data pedigree, which has direct relevance to development environments such as that for MedID, seeks to explore the adequacy and acceptability of the pedigree and quality of the data used to develop the model. It is the primary focus of data credibility efforts herein for MedID. Per NASA-STD-7009A w/CHANGE 1, data pedigree is formally defined as "a record of the traceability of data from its source through all aspects of its transmission, storage, and processing to its final form used in the development of an M&S."

MD Credibility Assessment Levels

Under NASA-STD-7009A w/CHANGE 1, credibility assessment levels shall be indicated for all M&S development according to the summary provided in Table 3.

Table 3 – Credibility Assessment Levels for M&S Development

Level	Data Pedigree
4	All data are known & traceable to RWS with acceptable accuracy, precision & uncertainty
3	All data known & traced to sufficient referent. Significant data has acceptable accuracy, precision & uncertainty
2	Some data are known & formally traceable with estimated uncertainties
1	Some data are known & informally traceable
0	Insufficient evidence

It is envisioned that a single credibility assessment level, as defined in the IMPACT Requirements document (IMPACT-REQ-0007), will be specified for the database as a whole, in compliance with the NASA-STD-7009A w/CHANGE 1 standards. These standards state that "assessment of M&S development data at Level 1 requires at least informal traceability, while traceability becomes formal at Level 2 and the processes for establishing important data and estimating its uncertainty. Attaining Level 3 requires all data to be known and traceable, but with only important or key data to have acceptable accuracy, precision, and uncertainty. Finally, level 4 requires all data to have acceptable accuracy, precision, and uncertainty." Therefore, the IMPACT Requirements document will serve as the source of truth for the target data credibility levels for the data pedigree, specifically PTRS.IMPACT.091 and PTRS.IMPACT.100 regarding space and terrestrial considerations, respectively.

MD Resource Data Change Tracking

The sources and lineage of data that inform MedID should be fully traceable (to the greatest extent possible), including the capture of any changes that may deviate from the originally sourced data, as these can potentially impact the data pedigree. To ensure the capture and traceability of all such changes to resource data within MedID, all changes to MedID content will be traceable such that the heritage and the degree of changes to resource items within the current database (relative to those used in previous versions) will be preserved. These changes - accomplished via several internally programmed features within IMPACT-MD - include Resource Record Status, Versioning, Change Log, and an overview of each feature is highlighted in Figure 6.

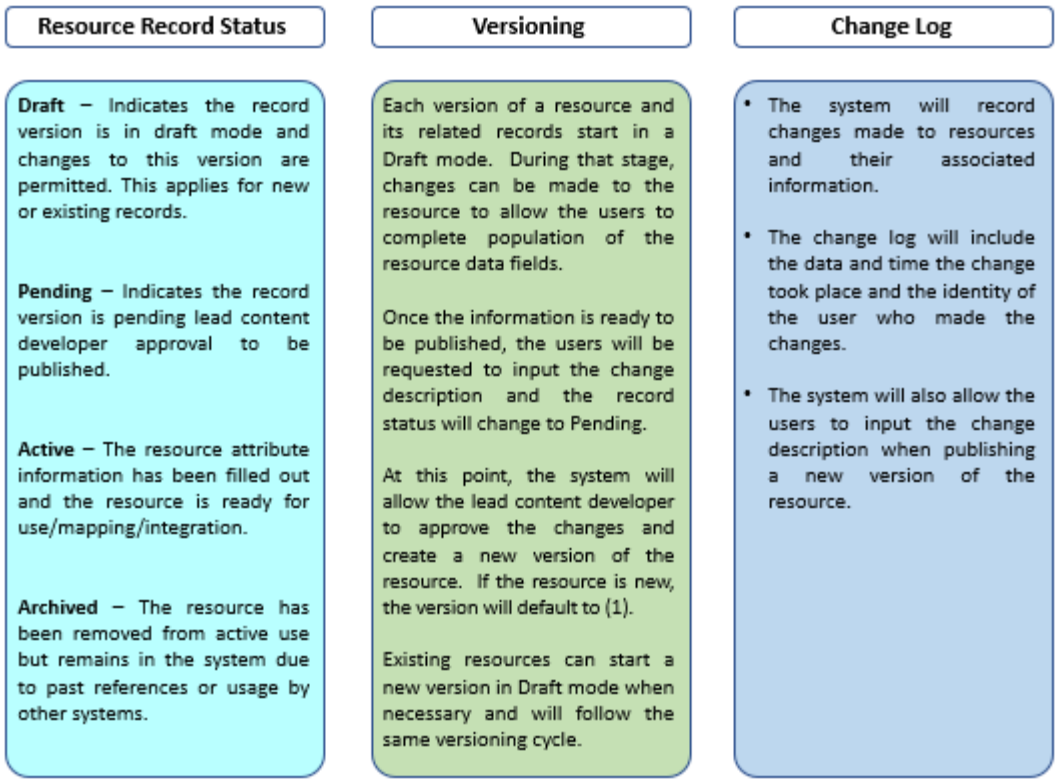


Figure 6 – MedID Resource Tracking Features

MD Credibility Summary

Maximizing the credibility of the resultant probability risk assessments (PRA) calculations generated via the MEDPRAT is predicated upon and facilitated by maximizing the fidelity of the data pedigree of the supporting clinical evidence and engineering data that inform MEDPRAT, namely the EL and MedID, respectively. Concerning the engineering data pedigree, the following data credibility foci for MedID data have been identified and addressed within this document in order to establish a level of certitude in the engineering data and the associated acquisition methods and are summarized below:

- What data will be collected:
    - Baseline data attributes for medical and pharmaceutical resource items (subject to resource taxonomy specifications) – mass, volume, dimensions, power, etc.
    - FOM and related information – mission information, operational environment metrics, shelf life, etc.
- Where it will be collected from:
    - Original Equipment Manufacturer (OEM) manufacturer/vendor sources – pre-vetted data published on manufacturer/vendor websites

  - US Government sources – US Government agencies or commissions (Food & Drug Administration (FDA), Consumer Product Safety Commission, PubChem, DailyMed, etc.)

  - Independent third-party sources – Underwriters Laboratories, US Pharmacopeia, Emergency Care Research Institute (ECRI) (an independent non-profit organization focused on healthcare safety, quality, and cost-effectiveness), DrugBank, etc.

  - Direct, protocol-driven measurements conducted by authorized clinical/technical staff

- Who will collect it – MedID Lead Content Developer, Lead Programmer, associated support Content Custodians (as needed), and authorized clinical/technical staff (in the case of direct measurements)

- How it will be collected – see Data Population (Section 3.2)

- Data traceability path – verified, documented links to referenced websites and other vetted sources, as well as internal tracking features within MedID (Section 4.2 - Figure 6)

- Limitations – see Data Content Limitations (Section 5.0)

DATA CONTENT ASSUMPTIONS AND LIMITATIONS

While every effort is made to ensure the accuracy and completeness of the engineering data content for MD, the following limitations and constraints are known to exist:

Item number	Assumption	Limitation
1	For cases where exact mass and volume are not explicitly known (or published) for a resource item, estimates of these entities are generally calculated via basic length x width x height measurements.	Thus, any empty spaces, odd shapes, or design voids within an item (due to internal or external contours or spaces within the footprint) remain unaccounted for by default, which may overestimate mass and volume values in some cases. Therefore, any data subject to these estimations shall be flagged or marked for full disclosure regarding the uncertainty in the measurement(s).
2	Specific details on packaging attributes for each item are currently unaccounted for in MedID (as of IMPACT v0.1) due to complexities in	User-specified packing factors may not be accurate or well represent the real-world packing arrangement, thus introducing some uncertainty in total mass and volume

	how the individual items are dispositioned for flight. While MEDPRAT does not explicitly assume or account for packaging, an IMPACT user has the ability (external to MEDPRAT) to manually prescribe packing factors that represent packing efficiencies for each resource item (with a packing factor of 1.0 equaling perfect packing efficiency) via the manipulation of mass and volume values that account for the desired efficiency within an IMPACT input file.	values. In addition, it is currently unknown how or whether packaging information may be introduced in future versions of IMPACT-MD.
3	Some data regarding COTS items may only be characterized in the context of terrestrial applications.	It may not be possible to provide 100% data completeness for every resource item depending upon the availability of quantitative information due to using COTS items in exploration environments.
4	Explicit contents of crew members' personal Medical Accessory Kits (MAKs) are subject to medical privacy regulations, and specific data and attributes (mass, volumes, etc.) are thus unavailable regarding those specific items.	Because the specific content, and thus associated masses and volumes, of crew member MAKs will vary with the needs of each crew member, MAKs will not be included explicitly in the MedID inventory, and any known averaged mass or volume associated with the kits will be subtracted from that of the overall totals for the medical system.
5	Some resource "costs" and constraints for equipment, devices, and other resources are difficult to quantify. Resource "costs" are considered herein as either 1) quantifiable (e.g., mass, volume, power, etc.) or 2) difficult to quantify (e.g., knowledge/ skills/ abilities, training, degree of autonomy, etc.).	There is a possibility that all "costs" per resource may not be known with certainty, resulting in (possibly unknown) uncertainty or inaccuracies in the total "cost" of each capability.
6	The storage of engineering data at (up to) six decimal places within MedID will facilitate/preserve data accuracy and accommodate the reporting of smaller masses and volumes in larger	Those engineering data collected from published references for individual resource items will be subject to the limitations (decimal point, etc.) of said published values.

	default units (e.g., reporting milligrams in terms of kilograms).	
7	Candidate resource items for the MedID inventory were chosen based on the best understanding (at the time of data research) regarding the functional intent and requirement for the item related to fulfilling its role in treating the associated medical condition.	Some resource items may be swapped out for alternate selections if/when more clarity or information regarding any evolving requirements becomes available.
8	Given that IMPACT is agnostic of candidate vehicle/habitat engineering designs for missions and mission segments, a given resource item's compatibility concerning vehicle mechanical, electrical, or other system interfaces and engineering requirements (e.g., power limits, electrical shielding, etc.) cannot be known *a priori* when selecting the appropriate resource item and is *de facto* assumed to be 100% compatible.	Some resource items selected for inclusion into MedID (especially those subject to vehicle operational interfaces and limits) may not represent an optimal selection concerning the overriding "real world" limitations that are ultimately associated with a final vehicle design selection. For example, the selected synchronized cardioversion device is assumed to be compatible with all vehicle electrical interface requirements and limitations with respect to voltage, wattage, etc. (if/when powered via the vehicle electrical system) and is likewise assumed to comply with all electrical shielding requirements.
9	Many/most candidate resource items for the MedID inventory are COTS-based selections. Resource item characterization in terms of mass, volume, and dimensions rely on published (or otherwise available) information.	In the absence of specific OEM specifications, the data used to characterize the resource items (e.g., shipping mass and dimensions) may be derived from a third-party vendor site and thus may be vendor dependent (as a result of vendor-specific packaging or estimations that were used in the derivation of that data).
10	The weblinks and sources for COTS-based resource items are assumed to persist over time.	Some reference or source links for COTS-based items are vendor-dependent and thus may become unavailable over time, pending the vendor's stock or product availability. While some internet archive websites are available to retrieve expired links, a secondary manual archival of the information pages for each resource item

		(including photos and relevant data) has been created via a catalog of captured screenshots.
11	COTS-based items are selected for inclusion in MedID strictly based on their potential to treat the required medical condition(s) specified by EL. Selection is agnostic of any other logistical (such as commercial pricing, vehicle/habitat compatibility, etc.) metrics.	Given that the Government routinely updates vendor-based contracts for procuring medical items for flight, the specific resource item chosen to fulfill a given resource role for a "real world" operational mission may change over time. Thus, the actual medical resource inventory items that may be flown in any given "real world" future mission(s) cannot be known with *a priori* certainty.

The above list highlights the most significant limitations that the MedID team is aware of in this document preparation, but this list is not considered a complete accounting of all limitations, both known and unknown. As such, the limitations presented in this list should serve as contextual boundaries within which the data and data attributes are indicated to be presently known or assumed, and the intention is for this list to serve as a guide from which to inform further content data and population efforts for future efforts.

APPENDIX A – REFERENCE DOCUMENTS

The following documents contain supplemental information and provide detail and guidance for the content contained within this MedID Content Development Methods document. Note: these documents may or may not be specifically cited within the text of this document.

Document Number	Document Title
HRP-43038	IMPACT Project Plan
HRP 48020 A	IMPACT Concept of Operations
IMPACT-REQ-0007	Project Technical Requirements Specification for the Human Research Program (HRP) IMPACT Tool Suite for the Exploration Medical Capabilities (ExMC) Element
IMPACT-PLN-0013	IMPACT Compliance Plan for NPR7150.2C
IMPACT-PLN-0014	IMPACT Compliance Plan for NASA-STD-7009A
IMPACT-PLN-0002	IMPACT Configuration Management Plan
IMPACT-PLN-0037	IMPACT Transition to Operations Plan
IMPACT-DOC-0004	IMPACT User Manual
HRP-48036	Evidence Library Methods (White Paper)
IMPACT-ANA-0010	IMPACT Sensitivity Analysis Report
IMPACT-PLN-0040	IMPACT Maintenance and Operations Plan
HRP-48012	Recommendation for a Medical System Concept of Operations for Gateway Missions
JSC_67070	Medical System Concept of Operations for Mars Exploration Mission-11
JSC-65722	Exploration Medical Condition List, Rev C
IMM-GEN-302	IMM Clinical Finding Forms Overview
IMM-GEN 309, Rev 1	IMM Medical Conditions List
HRP-47077	Integrated Medical Model Conceptual Model Document
HRP-48020	IMPACT Concept of Operations
iMED Lock Down 68	iMED Database
HRP-48039	IMPACT-Medical Database Project Plan
Currently unpublished	IMPACT-Medical Database User's Manual version Beta
IMPACT-CONOPS-0032	IMPACT-Medical Database Concept of Operations
IMPACT-REQ-0033	IMPACT-Medical Database Requirements
IMPACT-REQ-0007	Project Technical Requirements Specification (PTRS) for the IMPACT Tool Suite
IMPACT-PLN-001	IMPACT Project Plan
IMPACT-SDD-0009	IMPACT Software Design Description
IMPACT-DOC-0004	IMPACT User Manual
CCMP-MEDPRAT-DOC-001	MEDPRAT Concepts / Capabilities / Functional Requirements
CCMP-MEDPRAT-DOC-002	MEDPRAT User's Manual
CCMP-MEDPRAT-DOC-003	MEDPRAT Software Design Document
Unpublished	Evidence Library Pilot Project Final Report - EL PP Toxic Exposures and Injuries Condition List - EL PP REP Study Condition List - EL PP Spaceflight Condition List
NASA-STD-7009A w/CHANGE 1	NASA Technical Standard: Standard for Models and Simulations

Unpublished	Evidence Library Team Condition List
TBD	ExMC Medical System Foundation for Level of Care IV Short Duration Lunar Orbit V 1.0

ADDITIONAL REFERENCES

[1] Integrated Medical Model Overview, J. Myers, et al., Human Research Program Investigators' Workshop (HRP IWS 2015), Galveston TX.

[2] Exploration Medical Capability Medical System Recommendations for Gateway, M. Hailey, et al., Human Research Program Investigators' Workshop (HRP IWS 2019), Galveston, TX.

[3] Medical System Foundation for Level of Care IV Short-Duration Lunar Orbit: Context, Process, and Project History, NASA TM-20205010009.

[4] Medical Item Database: Accomplishments and Lessons Learned from the Evolution of MedID, Harrivel,* A., Lake,* R., Mosher, T., Nagel, C., Levin, D., Daiker, R., & Maddock, S., NASA's Human Research Program Investigators' Workshop (HRP IWS 2021), February 3, 2021, virtual event. **co-first-authors*

APPENDIX B – CURRENT MEDID FIGURES OF MERIT (FOMS)

FOM Attribute
Affected by Humidity Level
Affected by Pressure
Affected by Radiation
COTS
Development Level
FDA Approved
Operational Environment
Operating System* *(incorporated as an outcome of the IMPACT SRR)*
Potential Electromagnetic Interference (EMI) Effects
Produces Waste
Requires Acoustically Quiet Environment
Requires Gas
Requires Ground Communications
Requires Sterilization
Requires Thermal Control
Requires Vacuum Source
Requires Vehicle Power
Requires Vibrationally Quiet Environment
Requires Water Source
Resource Computer Dependency**(incorporated as an outcome of the IMPACT SRR)*
Sensitive to Microgravity
Shelf Life* *(incorporated as an outcome of the IMPACT SRR)*
TRL / PRL Technical Readiness Level / Pharmaceutical Readiness Level

APPENDIX C – EXAMPLE DATA COLLECTION WORKSHEET

Content Custodian Name:																	
	Resource Type designations: Bundle Consumable Device Hardware Lifestyle Nonconsumable Not Assigned Pharmaceutical Resupply Skill Software Supply Test Type			(T/F) responses: TRUE FALSE		TRUE FALSE	TRUE FALSE	TRUE FALSE	Available shapes: Cuboid Cylinder								
Resource Item	Details								Measurements								
Name	Resource Type	Manufacturer	Model Number	Parcel Qty (#)	Essential? (T/F)	Consum-able? (T/F)	Reusable? (T/F)	Test Data? (T/F)	Shape	Mass (kg)	Volume (cm^3)	Opera-tional Volume (cm^3)	Depth (cm)	Height (cm)	Width (cm)	Density (g/cm^3)	
	Consumable																

Content Custodian data worksheet

Available responses: 1 thru 3 4 thru 6 7 thru 9	Available responses: TRUE FALSE												Available responses: 1 : Concept 2 : Laboratory 3 : Relevant 4 : Space	O/S type for item	Available responses: TRUE FALSE *If TRUE, item requires interface with separate computer, please indicate type in Notes*
Pharmaceutical Info		Power								Batteries				Operational Environment			
														*new FOM (via SRR)	*new FOM (via SRR)	*new FOM (via SRR)	
PRL	FDA Approved?	Peak Power (W)	Avg Power (W)	Minimum Power (W)	Voltage (V)	Charge (A-hr)	Energy (kJ)	Input Impedance (MΩ)	Current (Amp)	*Volts*	*A-hr*	*Type*	*Charge Life (hr)*	Operational Environment	*Shelf Life (days)**	*Operating System/ Software**	*Has Resource Computer Dependency?**

Content Custodian data worksheet (continued)

Available responses: 1 : Concept 2 : Breadboard 3 : Prototype 4 : System or Item 5 : Flight Qualified	Available responses: 1 thru 3 4 thru 6 7 thru 9	Available responses: TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE	TRUE FALSE

Operational Environment																	
Development Level	TRL	Micro-gravity Sensitive?	Commer-cially Available?	Affected by Radiation?	Affected by Humidity?	Potential EMI Effects?	Affected by Pressure?	Requires Vehicle Power?	Requires Thermal Control?	Requires Water Source?	Requires Vacuum Source?	Requires Ground Comms?	Requires Sterili-zation?	Requires Vibrationally Quiet Envir?	Requires Acoustically Quiet Envir?	Produces Waste?	Requires Gas?

Content Custodian data worksheet (continued)

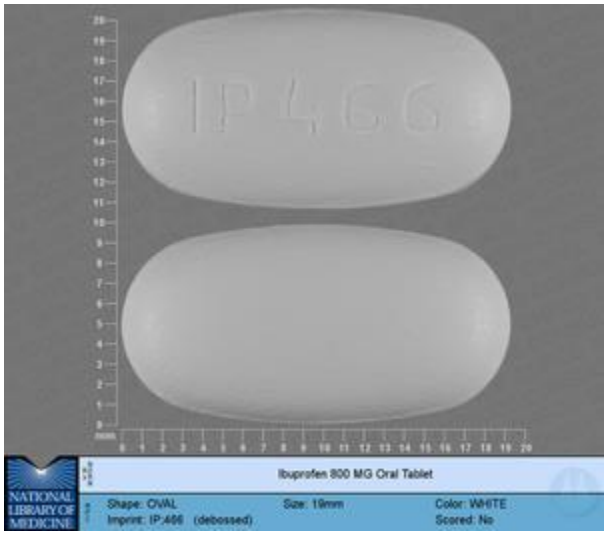
Mission Information		Source		Notes:	For MedID Content Devel/Verifier Use Only:
Storage:	Training:	Website:	Source Info: (incl. images, spec sheets, attachments,etc)		

Content Custodian data worksheet (continued)

APPENDIX D – PHARMACEUTICAL DATA COLLECTION

Estimation protocol for volume and mass:

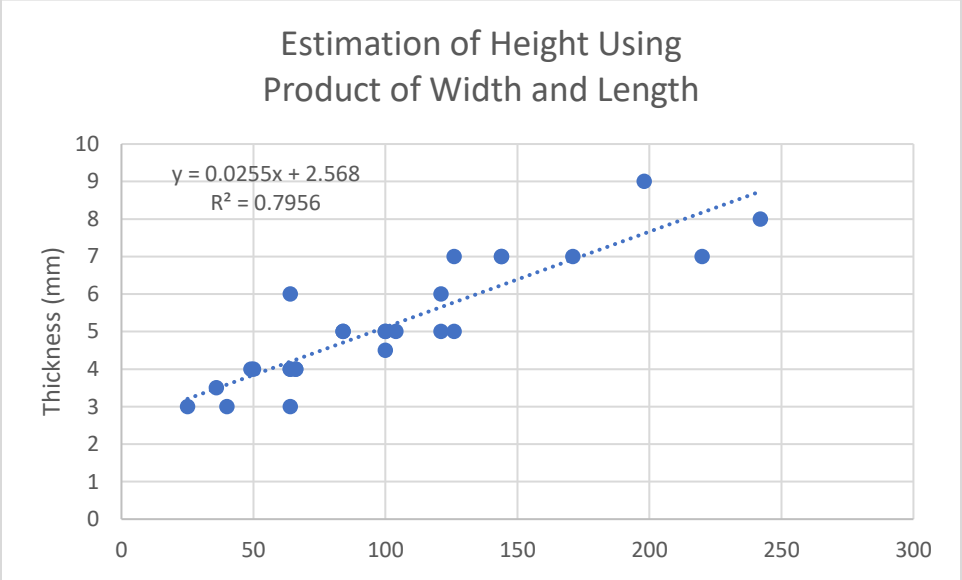
1. Table and capsule size estimation
    - Tablet and capsule 2-dimensional sizes were estimated from images available from NDCList.com, which is the complete repository of National Drug Codes (NDC) Information. https://ndclist.com/ndc/53746-466/package/
    - Only images with scaled measurements for length (x-axis) and width (y-axis) were used. For example:



Authors acknowledge the National Library of Medicine.
https://www.ncbi.nlm.nih.gov/home/about/policies/

    - Thickness (z-axis) information is not available from any images, except for gelatin capsules, as these are cylindrical in shape (y-axis = x-axis). For this reason, the thickness of compressed tablets were estimated using a sampling approach.
    - Modeling the total mass and volume:
        - Twenty-eight compressed tablets with shapes classified as "round," "oval," and "capsule" (compressed capsule, not gelatin capsule) were physically measured along all three axes using a caliper to within the closest millimeter.
        - Plots were generated to visualize these compressed tablets' length:height, width:height and length*width:height relationship. For each plot, a best-fit trend line was plotted in Excel, and the formula of the regression line was captured for each trend line.

- To evaluate the predictive performance of each model, the mean squared error (MSE) was calculated for the difference between each data point and the regression prediction for that data point. The best-performing model used the product of length*width (MSE = 0.504), followed by estimation based on length alone (MSE = 0.57). On the other hand, thickness estimation based on only width was the worst-performing model (MSE=2.31).



- Volume estimation of oral medications:
  - The volume of compressed caplets (oval and oblong capsule-shaped) was estimated as a rectangular prism: V = length*width*height
  - Volume of round tablets was estimated as a short cylinder:

    $V = \pi * (diameter/2)^2 * height$
  - The volume of capsules was estimated as a long cylinder: $V = \pi * (width/2)^2 * length$

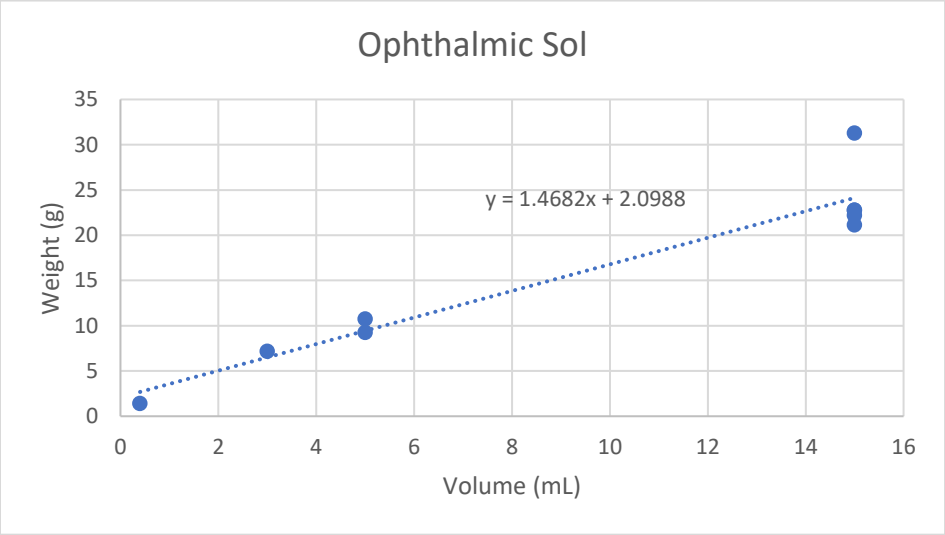
- Volume estimation of non-oral medications.
  - Size measurements for non-oral medications, including creams, ointments, otic or ophthalmic sprays, inhalers, vials, or ampules, were collected via various vendor websites (e.g., Amazon, Medline, etc.) as well as experimentally determined when possible.

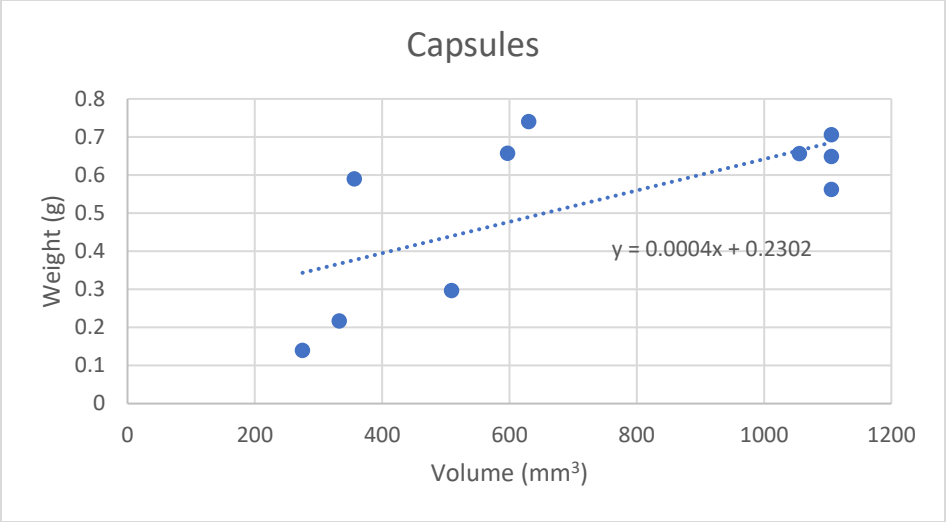
2. Estimation of product mass:
   - The product mass was estimated using masses provided by the NASA Operational pharmacists on 70 manually weighed medications. To the authors ' awareness, there is no public database that lists the weight of pharmaceutical products – only drug *strength* is

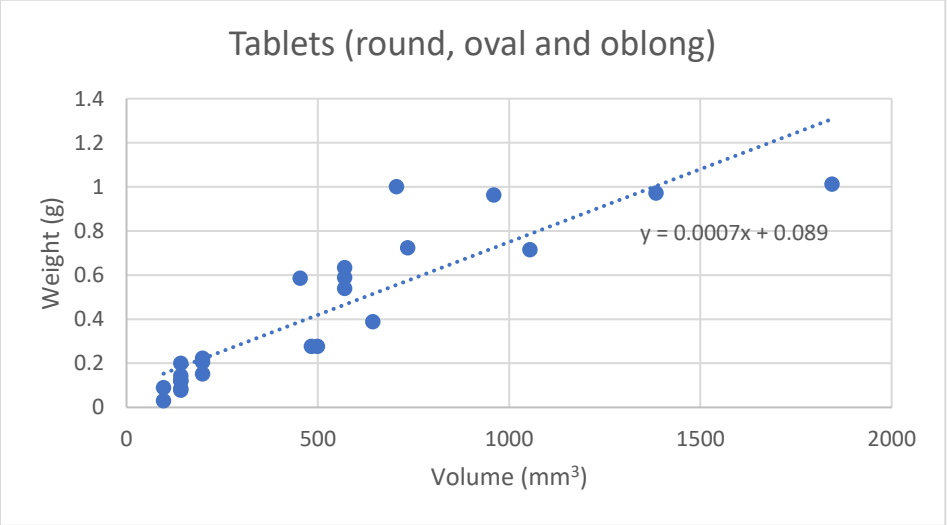
available. It is noted that no sizes were provided for any medications by NASA JSC Pharmacy Operations pharmacists; therefore, it is not possible to use provided information to estimate the size and 3-D volume of medications. The data provided consisted of representative masses for the following drug items:

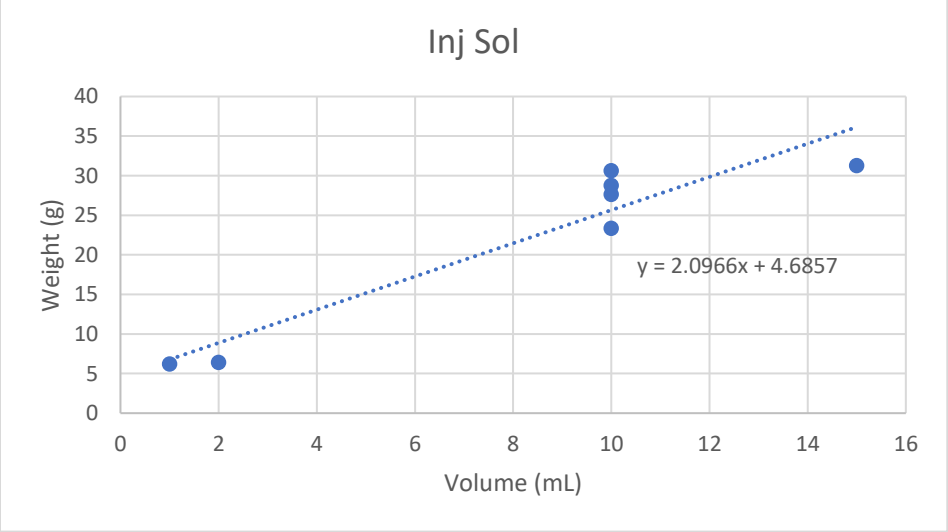
Dose form	Number provided	Dose form	Number provided
Oral inhaler	1	Nasal inhaler/spray	1
Lyophilized injectable powder	1	Ophthalmic solutions	8
Capsules	11	Topical cream/ointments	6
Oval tablets	9	No pharmacy information	3
Round tablets	17	Misc.	4
Injectable solutions	7		

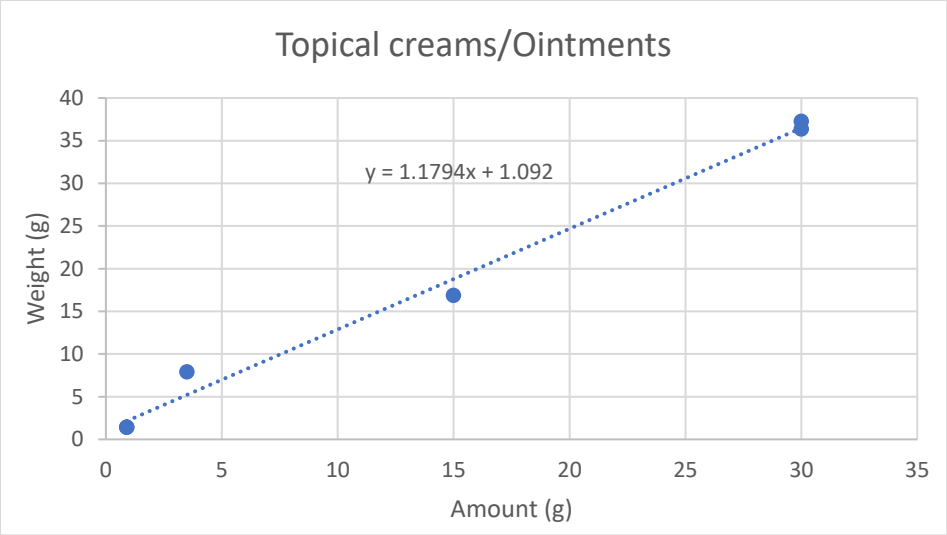
- From the provided data, a simple trend line was fitted to the weight data as a function of either drug volume (i.e., ml) or size/volume (mm^2), as determined for each oral medication as described above, or package size (i.e., 5 ml of solution (Sol)).




Capsules
Weight (g)
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
200
400
600
800
1000
1200
Volume (mm³)
y = 0.0004x + 0.2302


Tablets (round, oval and oblong)
Weight (g)
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
500
1000
1500
2000
Volume (mm³)
y = 0.0007x + 0.089


Inj Sol
Weight (g)
40
35
30
25
20
15
10
5
0
0
2
4
6
8
10
12
14
16
Volume (mL)
y = 2.0966x + 4.6857



- The mass of each pharmaceutical tablet, capsule, injectable solution, cream/ointment, and ophthalmic/otic solution was estimated using the formula of the trend lines.
- A ratio approach was used for vials of lyophilized drugs based on the weight of a vial of 1 g lyophilized ceftriaxone powder. The weight of the drug was subtracted from the total weight of the drug + packaging to obtain the empty vial weight. It is acknowledged that this assumption will likely underestimate total drug weight – that is, the total weight of lyophilized powder containing 1 g of ceftriaxone is greater than 1g because it also contains excipients. For other lyophilized drugs, the package weight was added to the drug weight, which is expected to partially cancel out the error associated with underestimating the weight of ceftriaxone. It is expected that the most significant source of error in this approach is the assumption that the vial sizes are similar across several drugs.

3. Operational environment assumptions and descriptions:
   - *Resource Item:* Systematic custodial name, dose, route, and dosage form. Corrected spelling errors, strength inconsistencies, and other errors when present. This description represents the recommended nomenclature.
   - *Representative Manufacturer NDC.* For medications with size and weight information, this column indicates the National Drug Code (NDC) identified for the exact product weighed or measured.
   - *Shape:* related to any product that was measured. Shape indicates how volume was calculated – either as a cylinder or cuboid.
   - *FDA Shape Code:* This code is the exact indicator of the shape of each oral pill. These codes are only applied to solid oral medications.
   - *LibOfMed Code:* This is an unambiguous code used by the National Libraries of Medicine (NLM) to identify drug products. This code, RxNorm concept unique identifier (RxCUI) is

the same for all equivalent brand and generic medications. In addition, this code can be used to recall any specific drug or NDC from the DailyMed, RxNav, or NDCList websites, and it also cross-references to DrugBank and US Pharmacopeia listings.

- *Mass estimate:* Estimated or measured mass of the representative drug products that were measured. Multiple available products may differ in size or mass for most drugs on the CRT list. Mass estimation is described above.
- *Volume estimate:* Volume data are estimated from representative medications. Because the NASA JSC Pharmacy Operations only weighed drug products, volumes are only available for solid oral medications (tablets, capsules, etc.).
- *Microgravity sensitivity*: All 'FALSE.' There is no reason to believe that microgravity affects the stability of medications, although administration of some medications in manufacturer packaging may be challenging.
- *Commercially Available:* All medications on the formulary are commercially available.
- *Affected by Ionizing Radiation:* The stability of many drugs is affected by ionizing radiation; however, these studies are generally performed to support pharmaceutical manufacturing and are carried out at radiation doses in the range of 25 kGy, and very high dose rates ranging in duration from seconds to a few hours. At such high radiation doses, when protected from oxygen exposure, solid medications are generally stable (although there are exceptions); aqueous drugs formulations, in the absence of radical scavengers, are generally much less stable.

  By comparison, the proposed career limit for ionizing radiation exposures for astronauts is 600 mSv (0.6 Gy), approximately 100,000-fold less than the dose used for pharmaceutical manufacturing. Assuming the cumulative dose of ionizing radiation during an exploration mission will be ~ 1 Gy (1 kGy = 1000 Gy), there are almost no empirical data on long-term drug stability in this dose range. Under the precautionary principle, it is assumed that drugs susceptible to degradation at high dose rates are proportionally susceptible to facilitated degradation at low dose rates. Therefore, drugs in an aqueous matrix are generally more susceptible to ionizing radiation than solid formulations. Therefore, solid medications are considered stable ('FALSE'); aqueous drug solutions are *potentially* sensitive ('TRUE').
- *Affected by Humidity:* Medications sealed in the manufacturer's packaging are considered to be protected from environmental factors, including humidity and oxygen. Medications that remain in manufacturer packaging include all topical, non-solid, liquid, injectable, and aqueous solution/suspension formulations. Most solid oral medications (i.e., tablets, capsules) are expected to be repackaged into non-protective packaging, similar to that used on the upcoming Artemis missions. Many of these medications are known to be susceptible to humidity. Therefore, all solid oral medications are considered susceptible to humidity under current NASA operational repackaging protocol for exploration missions; all other medications in manufacturer packaging are not expected to be susceptible until opened by the crew. Therefore, solid medications are assigned 'TRUE,' and all other not repackaged medications are assigned 'FALSE.'

APPENDIX E – GAP ANALYSIS DETAILS

Document title: MedID Gap Analysis *Authors: (NASA LaRC) Angela Harrivel, Renee Lake*	*Purpose: A gap analysis was performed on the attributes for the medical items in MedID to identify additional or expanded data attributes and/or categories that may benefit from further definition or increased detail/capability for resource items. Priority is given to those data attributes that will serve to improve risk analysis or otherwise facilitate trade study capability.*	*Annotations: Green shading indicates initial/general concurrence of MEDPRAT Lead and/or CST Lead regarding the proposed data attribute or gap.*

Data Attribute Category	Current State	Desired State	Gap / Question Identified	Expected Metric(s)	Corrective Action(s)	Originator (entity identifying gap/need)	Priority (L,M,H) (via ExMC Element)	Notes
Training / KSA / Expertise coding	No indication /does not exist in system	Inclusion of a stored /logged profile code to characterize the KSA required to optimally use a resource/medical item	What is the likelihood of successful use of device across operator type? How much training time is needed to use a resource? This addresses both the use and usability of devices by human operators, to improve risk predictions based on human data.	digit code	Develop and implement a training code that indicates level of KSA required to ensure correct use of item	MedID team with concur-rence from CST (Hailey)		MEDPRAT could potentially make use of this if enough information is available re: probability of success. Such information could be gathered/ generated via experimental study for critical devices
Digital data types		*Used to characterize and record the digital interfacing of the device*				CST & DA general concurrence		CST = Clinical Science Team DA = Data Architecture team
o single numerical values	No indication /does not exist in system	Inclusion of expected digital data output by or needed by the device, and how it is communicated (network message protocol)?	*What type of digital data does device/item provide? What type of digital data does device/ item need? This will be to charac-terize and record digital interfacing of the device to support Data Architecture or other efforts which could use digital integration information across devices /items*	data	Gather/obtain/ provide associated device digital data requirements for items to inform item characterization	MedID team		
o time series chart(s)	No indication /does not exist in system	Inclusion of expected files output by and/or needed by the device		data		MedID team with MEDPRAT concurrence		Would be useful to MEDPRAT from the perspective of crew risk; would support integration of medical item lists with Data Architecture design and modeling
o application-specific file(s)	No indication /does not exist in system	Inclusion of expected 'application-specific' file types; non-standard, proprietary or 'unique-to-device' file types		data		MedID team		
o 2D image	No indication /does not exist in system	Inclusion of expected files output by and/or needed by the device		data		MedID team		
o 2D video	No indication /does not exist in system	Inclusion of expected files output by and/or needed by the device		data		MedID team		
o sound /acoustic	No indication /does not exist in system	Inclusion of expected files output by and/or needed by the device		data		MedID team		
o none	No indication / does not exist in system	Device does not provide or need any digital data (e.g., gauze)		none or null		MedID team		

Data Attribute Category	Current State	Desired State	Gap / Question Identified	Expected Metric(s)	Corrective Action(s)	Originator	Priority	Notes
Figure of Merit (FOM) additions		***Include additional FOMs and/or data to increase available level of detail for resource items that may be factors in trade study analyses via:***						
Medical device reliability, failure rates or other characterizatio / quantification	No indication /does not exist in system	Inclusion of characterization/ quantification data regarding device reliability, failure rates, etc	Will the device remain intact and work as expected when needed?	data	Develop/obtain/ provide associated quantitative reliability data and prediction methods for item to inform risk estimates, document findings in the database	MedID team with MEDPRAT concurrence		Would be useful to MEDPRAT from perspective of crew risk
Maintenance requirements and/or minor repair possibil-ities	No indication /does not exist in system	Inclusion of main-tenance requirements for specific devices (to assess crew on-orbit workload, risk of broken equipment, consider if additional resources are consumed or if there are unique resource needs driven by maintenance /repair task	Will the device require main-tenance/minor repair?	data		MedID team with CST concurrence		CHS could potentially benefit from this, given interest in tying crew health state to the ability to perform tasks, but will require a lot of data and/or 'puzzle pieces'
Requirement for a backup device in case of breakage, fouling or damage	No indication /does not exist in system	Inclusion of any required backup devices	Will a backup device be needed?	resource item	Perform feasibility /trade study for backup devices. Specify quantity, type, modality of any backup devices required, document findings in the database	MedID team with CST concurrence		MEDPRAT essentially captures the concept of 'back-up' via alternate treatments, but does not include the likelihood the treatment fails, although could potentially consider this? Per CST: Think is captured in hardware criticality measure-ment from a vehicle perspec-tive, but good to think about as related to con-sumable items needed to clean/ disinfect to make it reusable. From a spaceflight perspective, if the medical system requires redundancy, it's always been captured by decisions to add multiples of things in the kits, as opposed to putting a criticality measurement against hardware. Most medical devices are not certified to fly as a standalone and criticality measurement is weighed vs the 'whole'.
Refinement of waste produc-tion breakout re: gas or liquid control required	No indication /does not exist in system	Indication of waste product type & controls required	Does item require gas or liquid control?	gas/ liquid	Specify/determine waste product type and control measures required, document findings in the database	MedID team		
Refinement of EMI status for item	No indication /does not exist in system	Indication of whether item produces EMI, or is susceptible to EMI	Does item produces EMI? Is susceptible to EMI?	produces EMI/ suscepti-ble to EMI	Verify/determine EMI status for item, document findings in the database	MedID team		
Requirement for operational communication bandwidth	No indication /does not exist in system	Identification/ quantification of any communication bandwidth requirements for item	Does the item require operational communication bandwidth?	data	Verify/determine communication bandwidth require-ments for item, document findings in the database	MedID team		

Figure of Merit (FOM) additions	**Current State**	**Desired State**	**Gap / Question Identified**	**Expected Metric(s)**	**Corrective Action(s)**	**Originator**	**Priority**	**Notes**
Assessing vibrational emissions from the item during use	No indication /does not exist in system	Identification of any vibrational frequencies produced by item	Does item produce vibrational frequencies during use?	data	Obtain validated frequency spectra of device in operation, document in database	MedID team		
Requirement for biosample / repository interface or disposition	No indication /does not exist in system	Identification of any interface or disposi-tion necessary for biosamples (live organisms, blood samples, etc)	Is a bio sample/ repository interface required?	data	Perform inventory review of any/all biosample-based resource items to assess toxicological status/ potential, document in database	MedID team with CST concurrence		CST sees as reasonable
$ Cost/time where resupply is a consideration	No indication /does not exist in system	Quantification of costs/time/logistics required for item resupply for missions where resupply is an option	In cases where resupply is an option, is resupply financially and/or logistically feasible?	data	Obtain estimates of costs, time and logistical metrics for resupply mission, document in database	MedID team		MEDPRAT does not consider resupply right now (it just simulates single stand-alone mission), but could be of interest at some point in future
Quantification of environmental requirements (broken out for use and/or storage)	No indication /does not exist in system	Identification of the actual range of variable or conditions (eg, humidity, temperature) during 'in use' and/or in storage or both	What is the appropriate range of conditions for resource item in storage and in use?	data	Determine/specify actual ranges of variable (eg, humi-dity, temperature, etc) for storage and 'in use' conditions, document in database	MedID team with MEDPRAT concurrence		Most useful if ranges or values (eg, temperature or humidity) could be tied to failure or probability of risk
Electrostatic discharge status	No indication /does not exist in system	Identification of potential for electrostatic discharge from item (may serve as an indicator for special handling by crew, special packaging required, operational risk)	Does the item produce electrostatic discharge?	Yes/No	Verify/determine electrostatic discharge status for item, document findings in the database	MedID team		
Status of resource item re: toxic elements/ properties (MSDS)	No indication /does not exist in system	Identification of toxic elements for resource item (may serve as prioritization or consideration for swapping out in trade study for item of lesser toxic status, as well as informing crew risk in handling/exposures)	Does the item contain toxic elements or properties?	data	Perform inventory review of all resource items re: toxicological status/potential, document in database with appropriate MSDS	MedID team with MEDPRAT concurrence		Would be useful to MEDPRAT from perspective of crew risk
Status of resource item re: radioactive properties	No indication /does not exist in system	Identification of radioactive properties within resource item (may serve as prioritization or consideration for swapping out in trade study for item of lesser radiologic status, as well as informing crew risk in handling/ exposures)	Does the item have radioactive properties?	data	Perform inventory review of all resource items to assess radioactive status/potential, document in database with appropriate MSDS	MedID team with MEDPRAT concurrence		Would be useful to MEDPRAT from perspective of crew risk

Figure of Merit (FOM) additions	**Current State**	**Desired State**	**Gap / Question Identified**	**Expected Metric(s)**	**Corrective Action(s)**	**Originator**	**Priority**	**Notes**
Requirement for calibration	No indication /does not exist in system	Identification of calibration requirements (and expiration dates) for resource item (may serve as a prioritiza-tion or consideration for swapping out in trade study for item of alternate calibration status, potential crew performance impacts)	Does the item need to be calibrated?	data	Perform inventory review of all relevant resource items to determine calibration status and requirements, document findings in the database	MedID team with MEDPRAT and CST concurrence		Per CST: Also, trying to delineate against manufacturer driven need to prove calibration vs NASA because its modified or used in an hazardous envir-onment. For example, ultra-sound does not normally need to prove that it takes good pictures, but may decide that we should check this periodically because of the high radiation environment.
Identification of shelf life for resource item	No indication /does not exist in system	Identification of finite shelf life for resource item (may serve as a prioritization or consideration for swapping out in trade study for item of alter-nate length shelf life)	Does the item have a finite shelf life?	data	Perform inventory review of all resource items to determine known shelf life status/ estimates, include this info in the database	MedID team with MEDPRAT concurrence		Would be useful to MEDPRAT from perspective of trade study and/or crew risk
Launch vs on-orbit vs return environment considerations (packaging, etc)	No indication /does not exist in system	Identification of changes in item disposition regarding packaging, etc that will change as a result of transition from launch to on-orbit to return (may serve as a prioritization or consideration regarding changes in mass & volume status for mission stages)	Does the item have status change or special handling/ considerations for launch vs. on-orbit?	data	Perform inventory review of all resource items re: packaging status/ estimates, docu-ment findings in the database	MedID team with MEDPRAT concurrence		Would be useful to MEDPRAT if missions are broken out into stages (which is not currently considered)
Transmitter status	No indication /does not exist in system	Identification of transmitter status for item	Does the item contain a transmitter?	Yes/No	Perform inventory review of all resource items re: transmitter, document findings in the database	MedID team		
Water (as a resource)	No indication /does not exist in system	Including water allows for prediction-based tradeoffs. Water not currently in medical system, but could be in future CHP system. Clinicians did not previously specify prevention, thus it was not included earlier. However, it could be used as treatment and/or prevention; could be important for liquid medications or saline generation.	Is water required as a separate resource?	data	Perform quantita-tive assessment of any prevention / treatment-based water needs, document findings in the database	MedID team with CST concurrence		Although water is technically a resource for missions already, it is not presently listed as separate resource within MedID and would need mass & volume assigned as an "individual item". Per MEDPRAT, the water requirement could potentially be 'backed out' via bundling. There are plans to include "preventive" capabilities in MEDPRAT.
Oxygen (as a resource)	No indication /does not exist in system	Including oxygen allows for prediction-based trade-offs. Could be used as treatment or prevention, and may be important in treatments for cond-tions (lung injury, DCS, altitude sickness, etc.)	Is oxygen required as a separate resource?	data	Perform quantita-tive assessment of prevention and/or treatment-based oxygen needs, document findings in the database	MedID team with CST concurrence		

Figure of Merit (FOM) additions	**Current State**	**Desired State**	**Gap / Question Identified**	**Expected Metric(s)**	**Corrective Action(s)**	**Originator**	**Priority**	**Notes**
Radial dimensions for items	No indication /does not exist in system	Quantification of radial measurements (radius, diameter) for circular or cylindrical items to improve mass & volume estimates	How to better quantify circular or cylindrical object shapes?	data	Inclusion of indicated dimensions available for circular or cylindrical items in the database	MedID team		
Shape of item	Cuboid or cylindrical only (at present)	Expand shape profiles to include circular/ global and other relevant shapes for items to improve mass & volume estimates	How to better classify non-cuboidal/non-cylindrical object shapes?	data	Inclusion of indicated item shapes in the database	MedID team		

APPENDIX F – ACRONYMS AND ABBREVIATIONS

API	Application Programming Interface
CM	Configuration Management
CMO	Chief Medical Officer
ConOps	Concept of Operations
CRT	Capability Resource Table
CST	Clinical and Science Team
DRM	Design Reference Mission
ECRI	Emergency Care Research Institute
EL	Evidence Library
EMI	Electromagnetic Interference
ExMC	Exploration Medical Capability
ExMCCB	Exploration Medical Capability Control Board
FDA	Food and Drug Administration
FOM	Figure of Merit
HEOMD	Human Exploration and Operations Mission Directorate
HRP	Human Research Program
iMED	integrated Medical Evidence Database
IMM	Integrated Medical Model
IMPACT	Informing Mission Planning via Analysis of Complex Tradespaces
IMPACT-MD	IMPACT Medical Database
ISS	International Space Station
JSC	Johnson Space Center
KSA	Knowledge/Skills/Abilities
LaRC	Langley Research Center
LevCare	Level of Care
LOCL	Loss of Crew Life
MAK	Medical Accessory Kit
M&S	Models & Simulations
MedID	Medical Item Database
MEDPRAT	Medical Extensible Dynamic Probabilistic Risk Assessment Tool
MSE	Mean Squared Error
NASA	National Aeronautics and Space Administration
NDC	National Drug Code
NLM	National Library of Medicine
OEM	Original Equipment Manufacturer
PRA	Probability Risk Assessment
PRL	Pharmaceutical Readiness Level
RTDC	Return to Definitive Care
RxCUI	RxNorm Concept Unique Identifier
SME	Subject Matter Expert
SQL	Structured Query Language
SysML	Systems Modeling Language
TRL	Technology Readiness Level

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