National Aeronautics and Space Administration


# THE INTEGRATED MEDICAL MODEL: OUTCOMES FROM INDEPENDENT REVIEW

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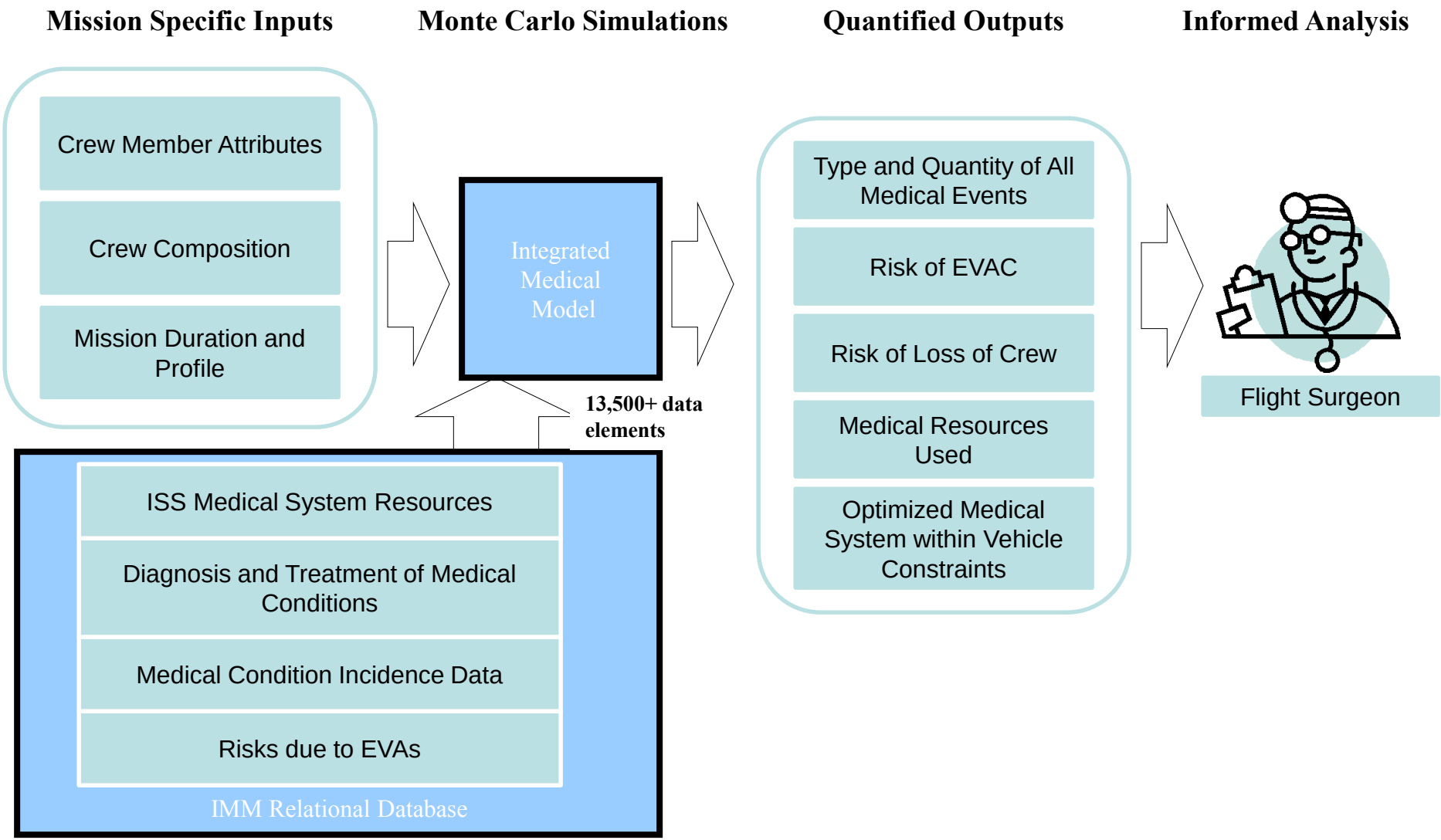
# Providing a tool to help informed decision making



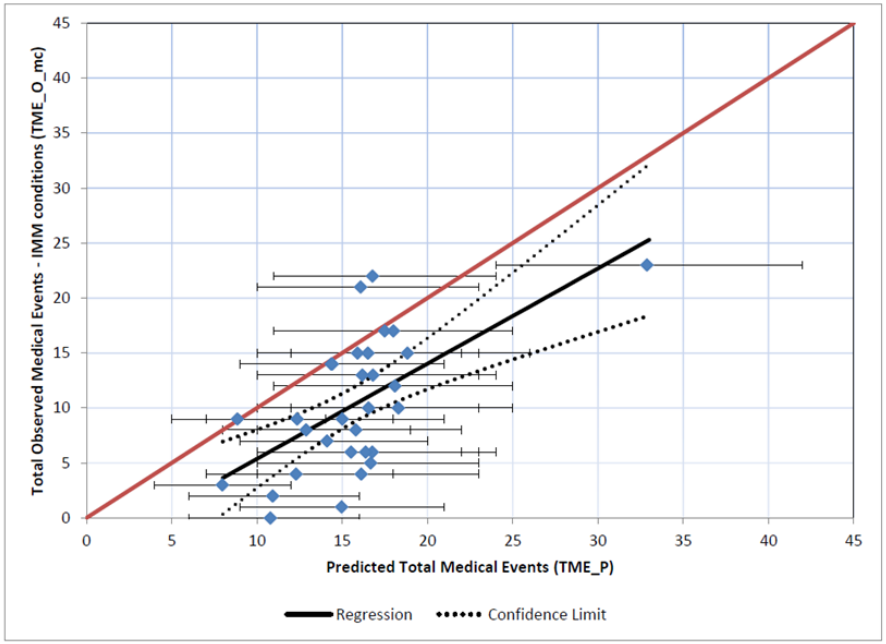
# IMM in a Nutshell

- **Platform to assess mission medical risk using proven risk assessment techniques.**
- **Platform for exploration of the medical kit trade space effects on risk.**
- **Gives decision-makers a means to balance medical risk with limited resources.**
- **Provides engineering teams with quantitative medical information to characterize risk.**

This is fundamentally about how the NASA Medical and Engineering communities communicate.

# Validation Against Real World Observations

- **Model validation utilized real world system (RWS) observations from International Space Station (ISS) Expedition (Exp) 14 through 39/40**
- **IMM simulation for each expedition**
  - Assuming ISS med capabilities, crew specific parameters and duration
  - Using data obtained from ISS missions and STS missions prior to referent
- **Total number, type and outcomes compared to RWS**



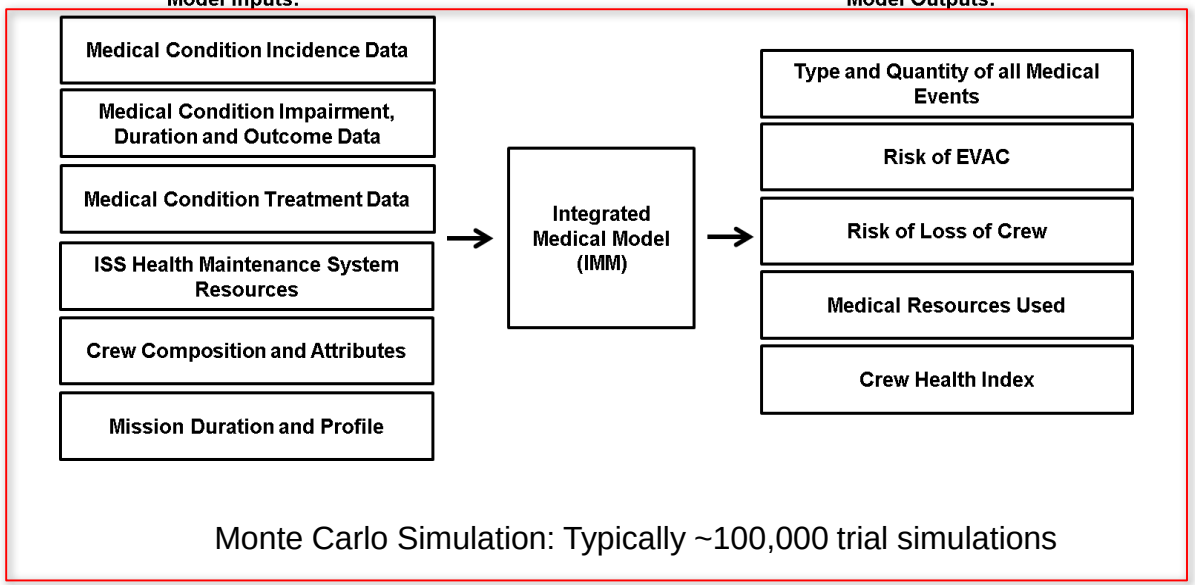

Snapshot of results for RWS ISS missions: IMM generally over-predicts by 3-4 medical events as indicated by regression intercept estimates and slope generally less than 1 (considering IMM Condition List events only).

# Model and External Review

Medicine
Epidemiology
Biostatistics
Software

Biostatistics
Modeling
Probability
Theory
Software

Aerospace
Medicine
Engineering
Software




Project
Management
Software

Review Expertise Needed in Red

# External Review Board

## ExMC convened an external review panel through the GSFC Systems Review Branch

- Chair: Dr. Bryant Cramer (GSFC – Retired)
- Review Manager: Mr. Neil Martin (GSFC)
- Aerospace Medical: Dr. Jan Stepanek (Mayo Clinic)
- Epidemiologist: Dr. Guohua LI (Columbia University)
- Chief Engineer /Software: Mr. Steve Scott (GSFC)
- Software: Mr. Robert Schweiss (GSFC)
- Biostatistics/Probability Theory: Dr. Nancy Lindsey (GSFC)
- Software/ Project Management:  Mr. Dick Kauffman (Criterion systems)
- Computational Modeling: Dr. Gary Pradhan (Mayo Clinic)

# IMM External Review

## From Nov 2015 to May 2016

- 2 Pre-Meeting Summaries : “Introduction to IMM” and “IMM Validation Strategies”
- Board formally convened three times Dec 2015, Jan 2016, March/April 2016

## External Review Topics

- Model Concepts and Software and code standards (i.e. JPR- 7150.2B compliance)
- Input pedigree of incidence and outcomes information (NASA-STD-7009: Input Pedigree Credibility Factor)
- Model performance (NASA-STD-7009 Verification, Validation, Sensitivity, Operations, Use History)

# Input Pedigree

Ensure internal processes for identifying, ranking quality, and including medical data with evidence-based rationale are appropriate to capture medical risk likelihood, medical information, and outcome uncertainty for the model application.

- Presented evidence related to data process and ~~data~~ capture
  - A selection of 10 Clinical Findings Forms (CliFFs) summarizing the types of data and conditions used to inform IMM simulations

    - Atrial Fibrillation
    - Burns Secondary to Fire
    - Decompression Sickness Secondary to EVA
    - Dental Abscess
    - Headache (Space Adaptation)
    - Hip-Proximal Femur Fracture
    - Eye Chemical Burn
    - Stroke
    - Sepsis
    - Urinary Retention (Space Adaptation)

# Summary Review Comments

**Board identified strengths:**

- **The concept of the IMM is scientifically sound and it works.**
- **The IMM represents a necessary, comprehensive approach to identifying medical and environmental risks facing astronauts in long duration missions.**
- **Because it integrates with the Exploration Probabilistic Risk Assessment (ExPRAT), the IMM has become an excellent tool through which engineers and physicians can better communicate with each other by speaking a common risk assessment language.**
- **The validation approach is sound and the use of actual space medical data is logical and compelling.**
- **IMM statistical methods for processing and analyzing the input data, performing simulations, and generating and presenting quantitative outputs are scientifically sound.**
- **The IMM validation approach is sound and the match between the IMM and the real world system is good.**

# Summary Review Comments cont.


**Board identified issues:**

- **Need for stronger software engineering involvement particularly in terms of quality assurance.**
- **Accuracy concerns regarding the CliFFs; the Board found a number of errors necessitating a robust review of all remaining CliFFs.**
- **Need for a sustainable approach to augment, peer review, and maintain the CliFFs.**
- **Organizational issues:**
  - Physical separation of Project Management from Development Team presents a challenge.
  - Evolutionary path for IMM insufficiently defined.
  - Need for a well-developed Operations Concept.

# RFA Summary

- **Total of 28 RFAs and 6 advisories submitted**
- **Project combined 8 of the RFAs for consolidated responses**
  - New total : ***24 RFAs***
- **RFA closure summary**
  - All submitted for closure as of 11/15/2016
    - 23 – Evidence or plan to secure evidence supplied as a response
    - 1 – Element and project decision not to pursue a response at this time
  - Closure acceptance received 12/2016

# Summary of Significant RFA Closure Activities

- **Code modifications were performed to reduce run times by 70%.**

- **Adjustments to reviewed condition information**
  - Minor typographical updates to DCS and Stroke CLIFF.
  - Updated data after addressing board suggestions and source data from the primary references.
    - Dental Abscess CLIFF – reevaluation of source data categorization of medical condition.
    - Space Adaptation headache leading to evacuation reduced from 1.5% max to 0% max.
    - Eye Chemical Burn – updated rationale.
    - Sepsis – updated rationale.

- **Developed survey document guidelines for improved configuration management of clinical data identification.**

- **Performed a calibration of CHI using the RWS and iMED data information (Accepted for Closure RFA 3.02).**

# IMM Project Planned Pre-Delivery Activities

- **Updated NASA-7009 Credibility Thresholds per accepted RFA plan (12/1/2016 – 3/7/2017)**
- **Complete STS RWS validation activity (12/1/2016 – 6/1/2017)**
- **Complete iMED 6.5 (12/5/2016 – 2/10/2017)**
- **Add RWS data to iMED 6.5 (3/31/2107 – 4/21/2017)**

# Conclusions

- **IMM is a tool intended to help mission planners make decisions regarding medical risk and supplies.**

- **It is intended to pull in data and experience to provide the best current information to inform medical resource planning.**

- **Outcomes of the IMM 4.0 review**
  - Definite need for the model of this type - validation testing illustrates its utility
  - Concerns expressed that the medical condition information requires further review
- **Forward work plan toward transition to customer baselined**
  - Final negotiation of ConOps plan with CHS
  - RWS validation for STS and RWS data integrated into iMED
  - Completion planned NLT 5/30/2017