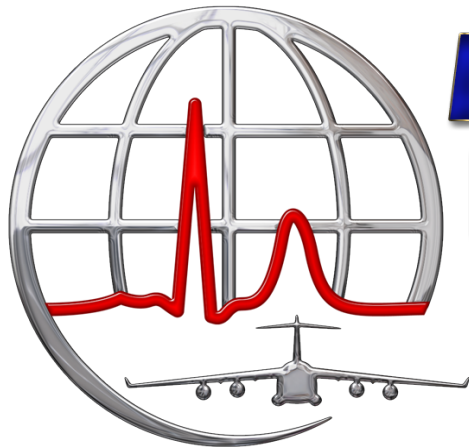


Headquarters U.S. Air Force

Integrity - Service - Excellence

Patient-Centered Precision Care



**AIR
FORCE
MEDICINE**

**Lt Col Cecili Sessions
Chief, AFMS Personalized Medicine**

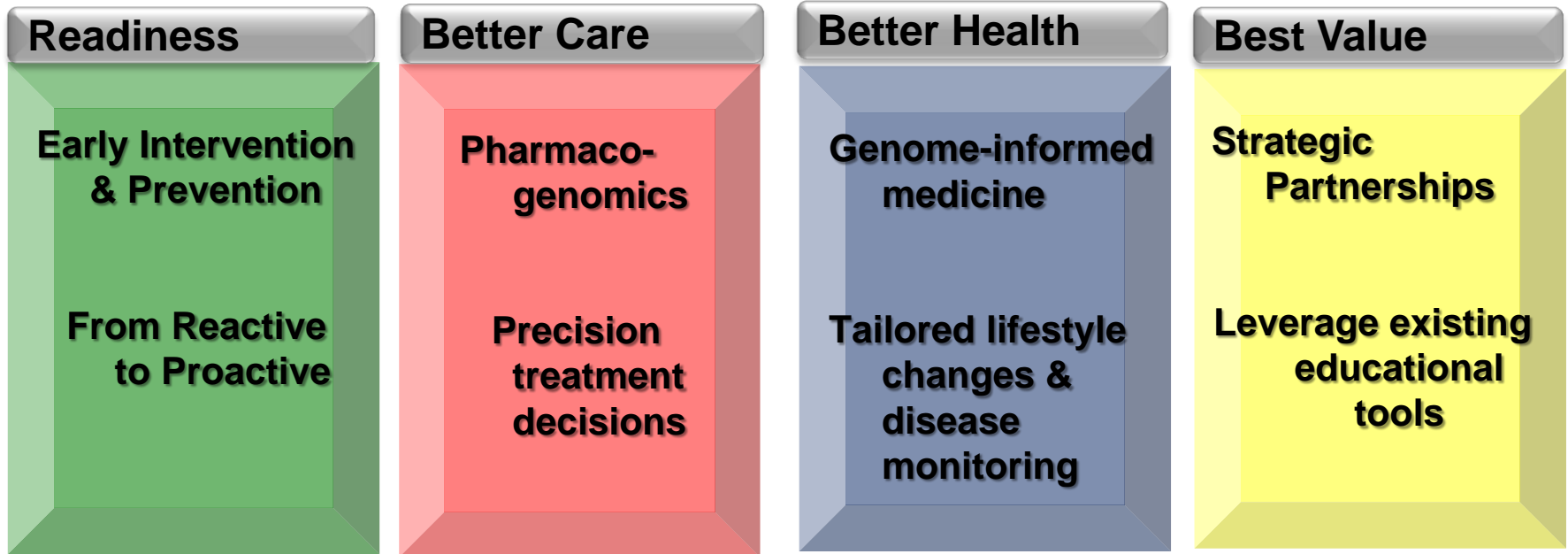
28 May 2013

Version 6



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Personalized Medicine and AFMS/MHS Goals



Patient-Centered Precision Care Program (PC2-Z)
AFMS comprehensive effort to prepare infrastructure for genome-informed personalized medicine and collaborate with academia, industry, and federal partners



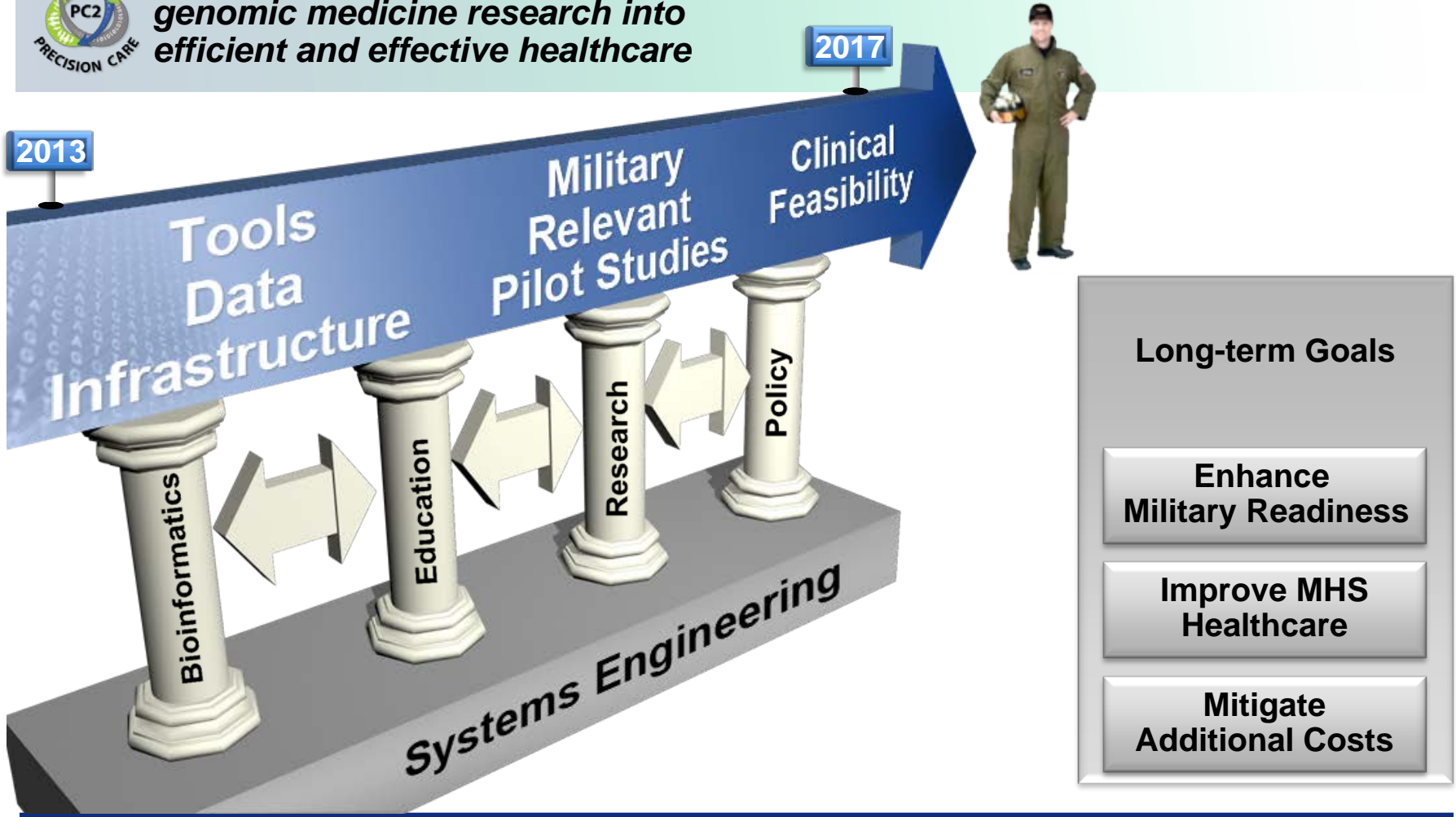


Patient Centered Precision Care PC2-Z

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To facilitate the translation of genomic medicine research into efficient and effective healthcare



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AF/SG Vision: Personalized Medicine

- **Galvanize MHS medical genetics research with AFMS seed funding and model collaboration, to create a strategic body of clinical knowledge**
- **Translate ‘omics into clinical practice**
- **Anticipate translation of rapidly advancing field of genomics/’omics into evidence-based, state-of-the-art care for our beneficiaries**
- **Complement the Patient-Centered Medical Home (PCMH) program by customizing prevention, detection, and treatment of diseases using ‘omics**
- **Leverage sister service support and collaborative partnerships to integrate genome-informed medicine across the MHS**
- **Utilize unique capability to demonstrate clinically actionable ‘omics by leveraging MHS EHR and beneficiary population (“the next Framingham”)**
- **Link informatics with ‘omics to accelerate the translation of medical knowledge, avoid duplicative testing, and support prevention workflow**



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AFMSA Personalized Medicine Research Portfolio (FY13)

- **Coriell Personalized Medicine Collaborative Clinical Utility Study (JHU/APL, Coriell Institute)**
- **Epigenetic biomarkers of stress at high altitude conditions (USUHS)**
- **GENERating Change: Genetic Risk Testing and Health Coaching (Duke Univ, Travis AFB)**
- **Genetically-Guided Statin Therapy (Duke Univ, Travis AFB)**
- **Cellular Sentinels Toxicity Platform (Sanford-Burnham)**
- **Identification of Associations Between Genetic Factors and Asthma that are Modified by Obesity (Yale Univ)**
- **Comprehensive Clinical Phenotyping and Genetic Mapping for the Discovery of Autism Susceptibility Genes (Nationwide & Dayton Children's Hospitals, WPAFB)**
- **Pending: A Rapid Learning System for Delivery of Personalized Healthcare (Duke Univ); Implementation, Adoption, and Utility of Family History in Diverse Care Settings (Duke Univ, Travis AFB)**



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Obstacles

- **Regulatory constraints: FDA, laboratory-developed tests**
- **National security concerns about biobanking, data sharing**
- **Information assurance: data storage/transfer**
- **Sequestration and priorities**
- **Operational vs. clinical 'omics**
- **Methods to leverage external expertise (contracting, partnerships)**
- **Ethical implications**
- **Privacy concerns and lack of coverage under GINA**



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GINA: Genetic Information Nondiscrimination Act (2008)

- **Protects individuals from discrimination by health insurers or employers based on genetic information**

- **GINA does not apply to**
 - **Members of the U. S. military seeking care via TRICARE/MHS**
 - **Veterans obtaining health care through the VA**
 - **Persons using the Indian Health Service**
 - **Enrollees in the Federal Employees Health Benefits (FEHB) Program – protected by Executive Order 13145 (2000)**





- **“The first civil rights bill of the new century of the life sciences”
(Sen Ted Kennedy)**
- **Non-disclosure vs. Non-discrimination**
- **Fear factor decreases research participation and may make patients reluctant to disclose clinically-relevant genetic data**
- **Special concerns for Service members**
 - **Lines blurred between employer, insurer, and healthcare team**
 - **Readiness and operational concerns trump confidentiality**





Precision Care Advisory Panel ***(PCAP)***

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- **Envisioned to provide service-specific operational and policy guidance to PC2-Z, and convened at the invitation of AF/DSG (Jul 2012)**
- **Core composition**
 - **Air Force, Army, Navy**
 - **HHS/PHS**
 - **VA**
 - **HA/TMA**
- **Clinical Proponency Steering Committee, chaired by DASD/C&PP, currently reviewing draft PCAP charter to task PCAP as work group to frame issues, gather data and develop MHS/DHA recommendations for genome-informed personalized medicine**



■ Proposed Objectives:

- Gather evidence to evaluate the translation of genomic-based personalized medicine into clinical workflow in the MHS/DHA
- Provide policy, scientific, and operational recommendations and approaches to support clinical genetic screening, counseling, and health care services for Service members and other MHS beneficiaries

■ Proposed Deliverables:

- Draft genetic information non-discrimination policy for DoD
- Create awareness of genomics/’omics within the MHS/DHA for the healthcare team and our beneficiaries
- Review existing constraints and deliver recommendations WRT genomic-based personalized medicine implementation in the clinical setting



Strategic Partnerships

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- **eMERGE Network – launched by National Human Genome Research Institute to integrate electronic medical records and genomics**
- **Institute of Medicine Genomics Roundtable**
- **Johns Hopkins University Applied Physics Laboratory – provides PC2-Z program integration and facilitates outreach with academia and industry as a University-Affiliated Research Center (UARC)**
- **Coriell Institute for Medical Research – research partner executing a longitudinal, prospective study to evaluate clinical utility of ‘omics**
- **Duke University Center for Personalized Medicine – leader in translating evidence-based ‘omics research into clinical practice**
- **National Coalition for Health Professional Education in Genetics**
- **Precision Care Advisory Panel – work group to frame issues, gather data, and develop MHS recommendations regarding clinical ‘omics**

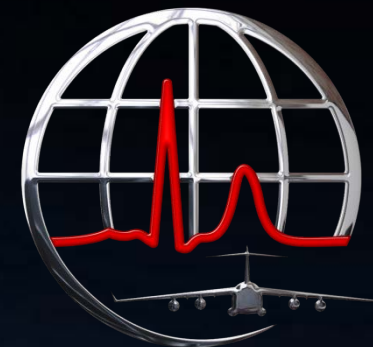


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Opportunities

- **Million Veterans Program**
- **Defense Health Agency**
- **Joint Program Committees (JPCs)**
- **“The barter system”**
- **Thank you, NHGRI!**

QUESTIONS?



A central graphic consisting of a silver pentagonal frame. Inside the frame is a globe divided into four quadrants. The top-left quadrant shows a soccer player in a white jersey kicking a ball. The top-right quadrant shows a person in a dark jacket using a handheld medical device. The bottom-left quadrant shows a person in a military uniform standing in a hospital or clinic. The bottom-right quadrant shows a person in a white lab coat interacting with a patient. The text 'Better Health' is written in blue along the top-left edge of the frame. 'Better Care' is written in red along the top-right edge. 'Ready' is written in green along the left edge. 'Best Value' is written in yellow along the right edge. At the bottom of the frame, the text 'TRUSTED CARE ANYWHERE' is written in blue. The background of the entire slide is a satellite-style map of the United Kingdom.



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PC2-Z Program Priorities & Proposed Future Efforts

FY11 – FY13

FY14 – FY16

FY17 . . . Beyond

Concept Development

Proof of Concept

Implementing into Clinical Practice

- Problem Definition
- Data Collection - Analysis
- System Concept
- Critical Technology Identification
- Demonstration
- Validation
- Prototyping

- Ongoing Data Collection
- Further Analysis - Feasibility
- System Requirements
- Design Developing with Stakeholders
- Address Policy Requirements
- Technical Evaluation
- Partnerships/Collaboration
- Reporting

- Joint Applications
- Transition of Products
- CONOPs
- Ongoing Testing and Evaluation
- Operational Utility Reports
- Review Policy Requirements
- Follow-on Review and Requirements

SYSTEMS ENGINEERING – PROGRAM INTEGRATION