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U.S. Department of Health and Human Services  
Room 434E, 200 Independence Avenue S.W.  
Washington, D.C., 20201

Attn: Personalized Health Care RFI

To Whom It May Concern:

This letter is written in response to the RFI on “Improving Health and Accelerating Personalized Healthcare Through Health Information Technology and Genomic Information in Population- and Community-based Health Care Delivery Systems”. The specific category of interest is:

- Concepts on anticipated approaches for the use of HER and population- and community-based health care system databases for longitudinal data collection in addressing:
  - Disease susceptibility
  - Clinical course and outcomes
  - Treatment response
  - Evidence-based clinical decision support
  - Optimal healthcare delivery systems

*Premises*

1. The Clinical Laboratory provides decision support for the majority of outpatient care. Routine examples include serum levels of: blood sugar; Hb1Ac levels; cholesterol and lipids; CA125; and Prostate specific antigen (PSA). When specific diseases are being managed (with diabetes being an obvious but not the only possibility), clinical laboratory values for Complete Blood Count (CBC); Flow Cytometry of circulating blood elements; serum drug levels; viral levels (e.g., viral RNA) and other molecular biomarkers is essential for tracking and managing clinical management and disease response. These laboratory findings constitute essential data for Evidence Based Medicine (EBM).
2. Anatomic Pathology also constitutes a key element of Evidence Based Medicine, including screening for and detection of cancer and pre-malignant states.
3. Virtually every clinical encounter for patients in the outpatient setting is marked by an interaction with the clinical laboratory. All inpatient clinical admissions are marked by interactions with the clinical laboratory.
4. Comprehensive compilation of clinical laboratory data (including Anatomic Pathology) for a defined patient population provides high-quality data for analysis of the following:
  - Frequency of patient care encounters
  - Utilization of the medical system (especially since ancillary utilization of healthcare services can also be tracked – pharmaceuticals, radiology, procedural intervention, hospital admission).
  - Quality of Care (since laboratory values report on the adequacy of patient care)

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## *Hypothesis*

Comprehensive capture of healthcare data from the Clinical Laboratory supports effective management of patient populations for:

- Disease susceptibility
- Clinical course and outcomes
- Treatment response
- Evidence-based clinical decision support
- Optimization of healthcare delivery

## *Proposal*

1. Complete capture of patient care data from the Clinical Laboratory enables:
  - Analysis of practice patterns of Physician Practices
  - Analysis of Quality of patient care
  - Comprehensive analysis of utilization of Health Care services
  - Critical data for analysis of the cost of medical care
2. Requirements for performance of this proposal include:
  - Electronic order/entry for participating Physician Practices
  - Comprehensive Clinical Laboratory database for the defined patient population
  - Electronic Healthcare Record data for the defined patient population
  - Access to laboratory claims/fee schedule/reimbursement data
  - Ideally, access to Medical and Pharmacy claims data
3. Analysis thereof then permits:
  - Identification of patient clinical outcomes, using direct and surrogate markers
  - Analysis of Provider laboratory utilization
    - Includes: use of laboratory data *content* as direct or surrogate markers of Quality of Care
  - Education of Physician Practices in Best Practices of Evidence Based Medicine
  - Critical decision-support for individualization of patient care
  - More effective management of utilization of Health Care services.

## *Preliminary Information*

The above practices have been conducted on a pilot basis by Cognoscenti Health Institute (“Cognoscenti”), Orlando, FL (Philip Chen, MD, PhD, Chief Executive Officer) in a ‘Wellness Program’ conducted for the Polk County School System, Polk County, FL. Cognoscenti has now partnered with the Department of Pathology, University of Florida, Gainesville, FL (James M. Crawford, MD, PhD, Chair and Co-Principal) for a more extensive pilot program currently underway with United Healthcare, in the Orlando/Central Florida region. These programs have the potential for substantial benefit to all of the following: patients; payors; employers; and healthcare providers.

## *Conclusion*

We consider that implementation of the above programming will be of substantial benefit to the American population, by providing major support for enabling health care practices to be patient-specific, and improving quality of care while reducing the costs of delivering healthcare. Moreover, establishing the infrastructure for Clinical Laboratory utilization will greatly accelerate the implementation of molecular ‘personalized medicine’ based on genomics, proteomics, metabolomics (& etc), through establishing the mechanisms for capture of laboratory data, in support of Evidence Based Medicine.

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Respectfully submitted,

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