


Wheels Within Wheels

COMPLEX Adaptive Systems Conference

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11-15-13

The Need for “Advanced CAS and CAS-Like Tool” Use by Healthcare Regulatory Agencies, Such as the US FDA—Especially While Reviewing and Approving Market Access to “Cost-Reducing” and “QOL-Enhancing” CAS and CAS-Like Products (Such as ACOs’ Population Management Software), for Use in the Care of Humans, First in the US and Then Worldwide



By
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11-13-13

Personal Background

- * **Best known for four key things:**
- * **First, Former Principal Deputy Commissioner (2nd-in-Command) of the US FDA**
- * **Second, Former Faculty Member at Harvard**
- * **Third, Founder and Former Faculty Editor-in-Chief of the *American Journal of Law and Medicine***
- * **Fourth, a Co-Leader, along with Bob Kelly and Others, of the Billion-Dollar-Turnaround of the Inventor of Laser-Eye-Surgery SW**

Background and Context

- * *As mentioned, I am a Former Principal Deputy Commissioner (“2nd-in-Command”) of the US FDA and a former teacher of regulatory and regulatory-science policy and law at Harvard University.*
- * **There are three key facts regarding my career that are relevant to this discussion.**
 - * **First, I serve on five corporate boards, four of which are healthcare-IT related.**
 - * **Second, I brought healthcare-IT to the FDA through a major reform effort that he co-led with Commissioner Frank Young.**

Background (Cont.)

- * **Third, I am, by persuasion and by the development of helpful technologies, systems, platforms, products, services, and especially “tools,” now focused on bringing a second major reform to the FDA.**
- * **The chief goal of this second major reform effort is to enable the FDA to work “faster, better, cheaper, and safer, as well as more ethically, more equitably, more efficiently, more sustainably, and more optimally,” in its review of new healthcare technologies, systems, platforms, products, and services (“products”) of corporate sponsors.**

Dual Use of this Approach: Once at Each Level

- * Interestingly, many of these products, themselves, have the promise to be faster, better, cheaper, and safer, as well as more ethical and more equitable.*
- * So timely approval of these "products" might both directly and indirectly help those who are interested in supporting the cause to lower the cost of key parts of healthcare some-ten-fold, worldwide, over the coming decade or at most two, thereby vastly improving timely access, worldwide, to desperately needed high levels of care.*

Becoming World-Class

- * As such, I am eager to see that the US FDA, and the world's other top healthcare regulatory agencies, including the EU's EMA, Singapore's HSA (the Gateway to Greater Asia), and Japan's PMDA, remain current in their use of "the world's most advanced regulatory and regulatory-science standards, methods, and tools."*
- * Right now, all of these systems are unlinked and are partially broken.*
- * There is absolutely no justification for the fact that a new drug, on average, costs some \$2 Billion and takes some 12 years to develop and to launch!!!!!!!!!!!!*

Especially Important, When Reviewing CAS Products, Such as ACOs' PM Software

- * This is especially the case, I believe, when the regulatory agencies are reviewing and approving market access for one of the many CAS or CAS-like technologies, systems, platforms, products, and/or services (“products”),*
- * such as ACOs’ “Population Management Software,” to themselves be used soon in improving the healthcare of humans—*
- * while dramatically driving-up QOL for patients and patients’ families, and dramatically driving-down the cost of such care for governments and insurance plan and self-paying corporate payers.*

Especially Important, When Reviewing CAS Products, Such as ACOs' PM Software (Cont.)

- * *In such cases, I argue, “advanced CAS or CAS-like tools” themselves must often be used by the regulatory agencies to review the adequacy of their brother and sister “CAS or CAS-like products,”*
 - * *(1) faster,*
 - * *(2) better,*
 - * *(3) cheaper, and*
 - * *(4) safer, as well as*
 - * *(5) more ethically,*
 - * *(6) more sustainably, and*
 - * *(7) more equitably*
 - * *(“better”), than would otherwise be possible to do, relatively speaking.*

Only Available True Path to Key Goals

- * ***Only in this way, I believe, can we reach, over the coming decade, our noble goals***
 - * ***(1) of reducing many areas of healthcare costs some ten-fold, and***
 - * ***(2) of improving worldwide access to care that***
 - * ***(a) is “sustainably” more safe, effective, and cost-effective (efficient), as well as more thoughtful and optimal, and that***
 - * ***(b) simultaneously fulfills our goals related to the seven “Ps.”***

The “Seven Ps”

- * ***The seven “Ps” include: Better care that is also:***
 - * ***(i) more personalized,***
 - * ***(ii) more predictive,***
 - * ***(iii) more preventive,***
 - * ***(iv) more patient-centric,***
 - * ***(v) more patient-valued (QOL),***
 - * ***(vi) more principled, and/or***
 - * ***(vii) more preemptive,***
 - * ***such as iPS-based regenerative organ adjunct-therapy (or “replacement-therapy”) might be, or as Big-Data-Analytics-based detections and management of pre-Diabetes or pre-Cancerous states might be, or as ACO PM Software managed care might be.***

Ultimate Goal: “True Healthcare Reform”

- * To accomplish “true healthcare reform,” instead of just “health-insurance reform,” which is what Obamacare (“ACA” or “The Affordable Care Act”) is all about, the far bigger problem needs to be broken into a dozen pieces, all of which can be addressed in parallel (rather than serially) in the next US President's four-year term.*

Teeing Up the US President

- * *To tee him or her up for major action three years from now, key homework must be done now. This homework would necessarily involve*
 - * *(1) forming a consensus on how to allocate issues into 12 discrete buckets, which buckets there are already 12 candidates for, including (a) cost-reform, (b) systemic-reform, (c) FDA-reform, and (d) medical-malpractice/products-liability-reform, and*
 - * *(2) deciding on how to smartly address the key issues placed in each of those buckets.*

Advanced CAS and CAS-Like Tools would be Extremely Helpful Here

- * *Advanced CAS and CAS-Like tools would be, I believe, extremely helpful in performing this “model-building” task, both within the context of a more optimized US FDA and in the context of a more optimized national and international society at large.*

The Models Developed Might be Applied to 200 Countries, Worldwide

- * *The Models developed in the US now, and refined later, can be used by us or others to extend true healthcare reform to some 200 countries, worldwide, where it is even more desperately needed than it is in the US.*

Distribution and Reuse Costs are Near Zero

- * *The beauty of CAS-software-based products, such as ACO-based PM software, is that they can be*
 - * *(1) transported,*
 - * *(2) translated,*
 - * *(3) customized,*
 - * *(4) installed,*
 - * *(5) implemented,*
 - * *(6) operated,*
 - * *(7) updated, and*
 - * *(8) upgraded*
- * *at very little additional cost, relatively speaking.*

FDA as a Special Use Case

- * The FDA represents a “special use case.”
- * It is so special because the FDA is the *de jure* “Gateway” to much of the US healthcare economy and the *de facto* Gateway to much of the WW healthcare economy.

FDA Reform

- * **“FDA Reform” is a big piece of “Overall Healthcare Delivery System Reform.”**
- * **Both are desperately needed.**

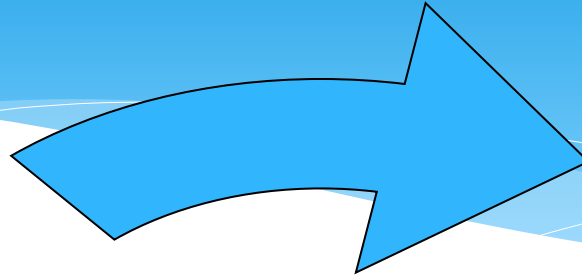
FDA Software Tool Reform

- * **“FDA CAS-Software-Based Tool Reform” is a big component of “Overall FDA Reform.”**

Upward-Cycle

- * **Per the next two slides, a cycling up of the FDA's new products review processes will lead to massive improvements (in terms of costs, safety, and effectiveness) to the US and WW healthcare delivery systems, through the massive improvements in products and the systems and systems of systems that they create or enable.**

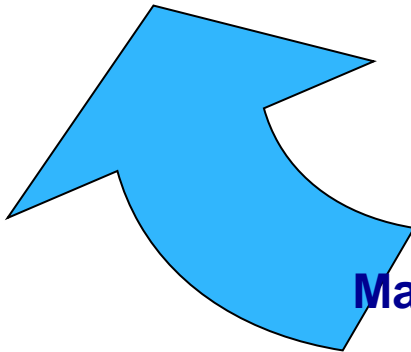
First Big Data Three-Legged Stool



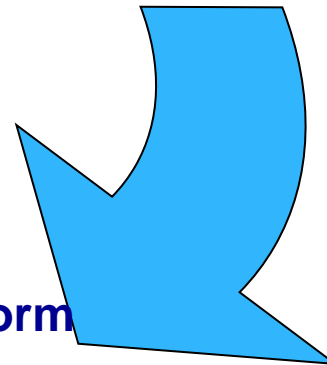
Personalized-Medicine-Reform

Massive FDA-Reform

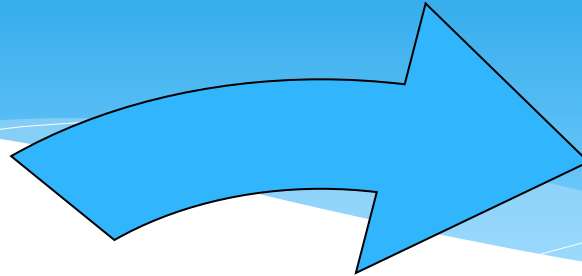
**Massive
Upward-Spiral
in Innovation
!!!**



Massive Healthcare-IT-Reform



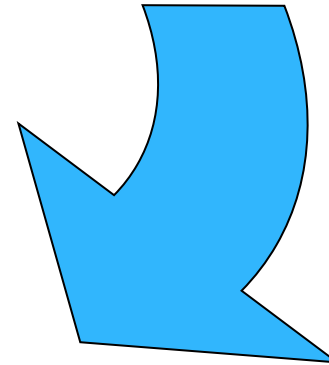
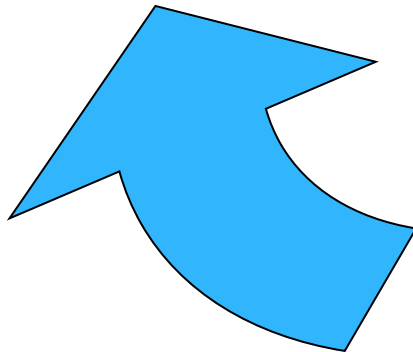
Second Big-Data Three-Legged Stool



Molecular-Diagnostic-Analytics

Digital-Imaging-Analytics

**Massive
Upward-Spiral
in Systemized,
Mechanized,
and Integrated
Healthcare !!!**



Electronic-Health-Record-Analytics and Internet Analytics

Why Big Data Analytics?

- * What kinds of differences can Big Data Analytics make?
- * There are five key impacts it will have on the roll-out and aggressive use of “Personalized Medicine” (the reverse of one-size-fits-all medicine)
- * These five key impacts are, that it enables users to:
 - * Make far better and far more specific detections, diagnoses, prognoses, etc.
 - * Far better select and target therapies, the first time and every time
 - * Far better predict courses of disease and courses of care, and far better assess patients’ inbred or acquired predispositions and inconsistencies
 - * Structure remaining non-personalized therapies, and far better understand which therapies work for more than one disease, and why
 - * Far better read, understand, and modify genetic structures, so as to prevent disease or to slow disease progression to more serious stages

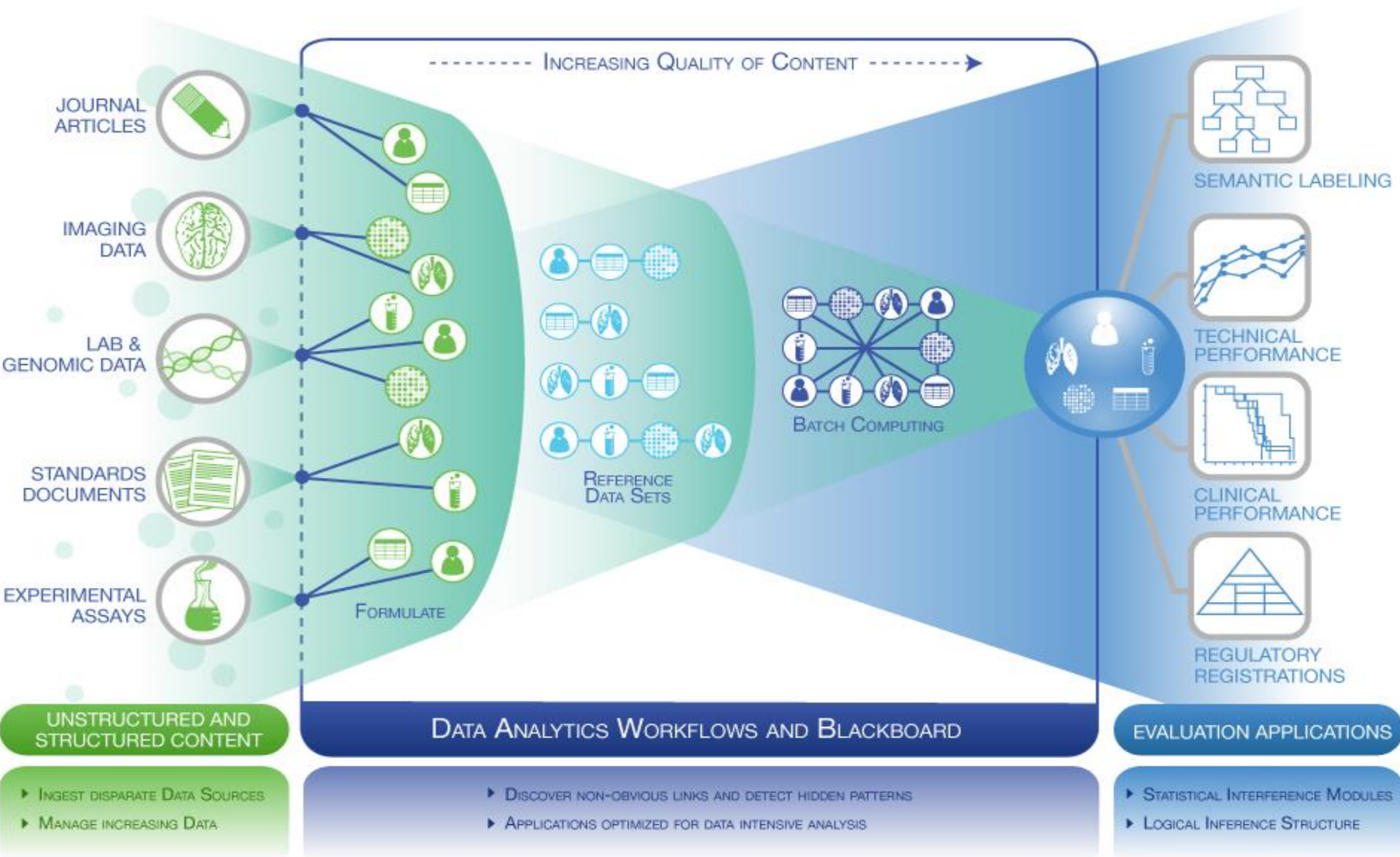
How Big Data Analytics Processes Work

- * Big Data Analytics Processes work as follows:
- * “Data” -> “Acquire + Retain” -> “Filter + Transform” -> “Pre-Process + Prep” -> “Discover + Explore” -> “Report + Analyze” -> “Automate + Systemize” -> “Post-Process + Interpret” -> “Business Users” Use to Complete Valuable Business Actions (i.e., Solve Key Problems)

Key Big Data Analytics Processing Goals

- * Faster, better, cheaper, and safer “discovery cycles” and “analytical value chains”
- * Faster, better, cheaper, and safer “insight discovery and exploration,” for use in solving business problems
- * Moving beyond “insights,” to “knowledge,” “wisdom,” and “actionable-intelligence” discovery and exploration
- * Bigger Volume, Greater Richness, Faster Pace
- * Continuous feed of data at high speeds, even real-time feeds
- * Not just “integrate” things (old school), but “pattern-recognize” things (new school), just like humans do
- * Move from using just “some” data, to using “all” data, at least to optimal sampling levels of data use
- * Achieve BOTH “high-flexibility” AND “fast time-to-value” (by improving TDWI’s (Teradata’s) Aster, for example, or Apache’s Hadoop, for a second example)

A Pictorial Example



Truly Robust Text-Analytics Engine Diagram

Norris Capital's and its Strategic Partners' Advanced Technologies and Products

LM's Advanced Technologies, Platforms, and Products

Hadoop
and Other Big Data SW Tools

Pig
and Other Big Data Languages

MongoDB, Cassandra, HBase
and Other Big Data Database Management System

Norris Capital's and My Grand Ambitions

- * **Norris Capital's and my grand ambitions, which have been frustrated for years, but will now be achieved, are to accomplish three key, world-transforming goals:**
- * **First, to, financially and psychologically, massively reward our loyal shareholders and partners for their generosity, intelligence, foresight, commitment, passion, and patience**
- * **Second, to drive down the cost of healthcare some ten-fold, WW, during the coming decade**
- * **Third, to automate or semi-automate as much of healthcare as is appropriate, and do so, while also making access, outcomes, quality, and safety of healthcare better, and while making providers and their employees more profitable and satisfied**

Tools Needed

- * **Chief among these desperately needed advanced CAS-based SW tools for FDA's use are:**
 - * **Big Data BI analytics, predictive-analytics, and prescriptive-analytics tools,**
 - * **Big Data BI text-analytics tools, and**
 - * **Big Data BI decision-support tools.**

Key Benefits of New FDA Tools

- * **The direct and indirect value of robust new FDA tools is almost incalculably large. Key among them are:**
 - * **The “Big Data BI Analytics, Predictive-Analytics, and Prescriptive-Analytics” tools enable the FDA to evaluate products much more quickly and much more equitably**
 - * **The “Big Data BI Text-Analytics” tool enables the FDA to continuously educate itself and evaluate products and trends through medical knowledge processing assessments of Internet and EHR data sources, and therefore to apply my “Pressure-Point-Regulation” Theory appropriately**
 - * **The “Big Data BI Decision-Support” tool enables the FDA to make better decisions far faster, and therefore to apply my “Pressure-Point-Regulation” Theory appropriately**

Other Benefits of New FDA Tools

- * **There are also other important benefits of the new FDA tools to the FDA, to Product Sponsors, and to Society:**
- * **They enable the FDA to far more efficiently and effectively solve:**
 - * **Multi-Objective optimization problems**
 - * **The who, what, where, when, how, and why problems of assigning and engaging new product reviewers**
 - * **Problems regarding resource allocations between and within projects**
 - * **Problems regarding methods mapping and best-practices rules discovery, development, and use**

Additional Benefits (One)

- * **Problems associated with “systems robustness determinations”**
- * **Problems involving tool and products affordability, efficiency, effectiveness, flexibility, scalability, and performance**
- * **Problems regarding the recording, understanding, verification and validation of the FDA’s decisions**
- * **Problems regarding the creation of evolving and self-adapting “systems of systems,” and self-optimizing of capabilities and other benefits of tools and of products**

Additional Benefits (Two)

- * **Problems associated with system and system of systems sustainability**
- * **Problems associated with generating accurate cost-effectiveness assessments of products to satisfy future demands**
- * **Problems associated with “truth modeling,” “hypotheticals testing,” and “simulations” needed for more “predictive” and more “prescriptive” assessments of tools (the FDA) and products (the Sponsors)**
- * **Problems in minimizing “unforeseen consequences and avoidable risks,” to minimize system risks and to maximize system benefits**

Additional Benefits (Three)

- * **Problems associated with sustaining a collaborative process for “risk-informed decision-making”**
- * **Problems associated with coming up with specific risk assessments, leading to specific risk-quantifications, not just crude “yes” or “no” determinations**
- * **Problems associated with eliminating decision-related biases, both real and perceived**
- * **Problems associated with eliminating counter-productive components of historical culture**

Additional Benefits (Four)

- * **Problems surrounding the instilling of a culture of high productivity and of “fast failures”**
- * **Problems of incorporating economies of scale and marginal cost assessment considerations into macro and micro decision optimization strategies**
- * **Problems associated with sustaining simultaneous convergent thinking and divergent thinking, as well as macro thinking and micro thinking, when complexity and conflict abounds**

Summary of Facts and Insights

FDA Software-Tools Reform

Today's Essential Need for Reform of the “US FDA's New Medical Device Product Review Methods, Standards, and Especially Big Data Analytics and Decision-Support CAS-Software-Based Tools”

Facts

- * **America is in desperate need for a set of new healthcare technologies, platforms, products, and services (“products”) that are “faster, better, cheaper, and safer, as well as more ethical and more equitable,” than her existing set of healthcare products.**
- * **She can no longer afford the exorbitant costs (financial, mental, emotional, and physical) associated with the current healthcare delivery system.**
- * **The current system is simply just not at all sustainable, long-term.**

Facts (Cont.)

- * **Researchers and developers are working on a new set of massively-cost-reducing products, chief among them, CAS (Complex Adaptive System)-software-based medical device products.**

Facts (Cont.)

- * **But all new medical devices, including new CAS-software-based diagnostic and therapeutic devices, must receive either “an FDA 510(k) approval” or “an FDA PMA approval,” if they want to lawfully access US commercial markets.**

Facts (Cont.)

- * **And, regrettably, the methods and standards that guide the FDA's decision-making processes here are not currently sufficiently up-to-date, or sufficiently advanced, for the FDA to accomplish this task, anywhere near optimally.**

Insights

- * **To remedy this, our goals as a society must be two-fold:**
 - * **To aggressively improve FDA's effectiveness and efficiency (i.e., to create a "faster, better, cheaper, and safer, as well as a more equitable and more ethical," version of the FDA, and, to accomplish this,**
 - * **To aggressively improve the methods and standards, and especially the "regulatory science" tools and other tools, especially software tools, that the FDA has available to it in making these decisions.**

Insights (Cont.)

- * **One of the best ways to accomplish these two goals, plus our overriding goal of creating availability of new sets of advanced and improved healthcare products, is to create a new set of “advanced CAS-based SW tools” for FDA’s aggressive use in its deliberative processes surrounding new product reviews and approvals.**

Insights (Cont.)

- * **Chief among these desperately needed advanced CAS-based SW tools for FDA's use are:**
 - * **Big Data BI analytics, predictive-analytics, and prescriptive-analytics tools,**
 - * **Big Data BI text-analytics tools, and**
 - * **Big Data BI decision-support tools.**

Insights (Cont.)

- * I have summarized some of the key benefits above
- * Clearly, there are many, especially once we determine that we are committed to creating a far better healthcare-delivery system of systems, including a far better FDA system

Insights (Cont.)

- * **These new FDA Big Data tools can most cheaply and most creatively be created collaboratively.**

Conclusion

- * **The Global Collaborative Center (GCC) is committed to helping us accomplish these goals, both in the US and around the world.**

Conclusion (Cont.)

- * **The GCC is the world's first global and cross-industrial network**
- * **(1) of world-class companies involved in researching, developing, manufacturing, marketing, and distributing Food, Drug, Device, and Healthcare “products,” including some of the world's most innovative “breakthrough” technologies, platforms, and products, and**
- * **(2) of companies wanting to use or invest in these products.**

Conclusion (Cont.)

- * **The Members of the GCC are partnering**
- * **(a) to work collaboratively together, and**
- * **(b) to promote lasting, long-term bountiful collaborative relationships,**
- * **for obtaining “faster, better, cheaper, and safer” regulatory approvals, from such world renowned regulatory agencies as the “US FDA,” the “Singapore HAS” (the Gateway to Asia), the “EU EMA,” and the “Japanese PMDA,”**
- * **all for the benefit of patients (and the patients’ families and their next generations) around the world, who have serious unmet medical needs.**

Conclusion (Cont.)

- * **With GCC's and its Members' aid, we can accomplish many of our goals before the end of the decade.**

Objectives: Prosperity, Health, and Happiness



Results

- * **Finally, there are many strong winds moving healthcare delivery in new directions:**
 - * **Personalized medicine is the strongest force right now**
 - * **Soon the systemization/mechanization/integration force and the automation/semi-automation/robotics force will take the lead**
 - * **There are also strong forces:**
 - * **for advanced “high-end patient-management, hospital-enterprise-management, and hospital-system-enterprise-management systems”**
 - * **for advanced “mid-level diagnostic, prognostic, and therapeutic machines,”**
 - * **for advanced “low-end (risk-assessment) products (such as serious iPhone Apps)”**
 - * **And for Truly Robust Text-Analytics Engines (Machines/Platforms) to soon populate the world**

Longest Journey Starts with a Single Step

- * Let's start with “Massive FDA Reform.”
- * And begin that with “CAS-software-based Big Data BI Analytics Reform.”

_____Thank You!_____

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