

Healthcare **D**ata **E**xchange **F**ramework (HDEF)

scalable economy of secure information and services

A pilot project executed within Research Collaboration Agreement between
US FDA and IBM Watson Health Group

HDEF pronounces as \ 'hā - ,def\

What should a good story have:

- **Challenge:** what is the problem we are trying to solve ?
- **Setup:** what do we have now ?
- **Development:** what actions did we take ?
- **Resolution:** how did we solve the problem ?
- **Poetic culmination:** what did we learn ?
- **Inspiring afterthoughts:** what will be next ?
- **Great title:** “ ... ”

Challenges: age of **data** explosion.

- **We all know FDA mission:** in brief, we are here to ensure safety and efficacy of medical products (before, during and after the product is in the market).
- **We need data:** preclinical, clinical, EMR, nutrition, wellness, pre- and post-market, statistical, genomics, metabolomics, adverse events, patient level, summary ... you name it.
- **Lack of standards:** not harmonized data and processes, ad hoc solutions are found on case by case, insufficient provenance.
- **Infrastructure needed:** lacking network throughput, always not enough compute and storage power, lack of expertise in new computational methodologies.
- **Inefficiencies:** administrative, legal barriers, and some “19th-century-cool” legacy technologies driving document and data flows.
- **Security keywords:** FedEx Truck, printed paper documents OCR, emails, unencrypted hard-drives, anonymization is considered security technology.
- **Ownership and access:** limited and cumbersome access to data through complicated DUA, IRB approvals, legal agreements, etc.

After all of this: our FDA scientists deserve a medal for doing this amazing work.

Challenges:

- Lack of incentives
- Lack of funding
- Fear of change
- Fear of burden

Setup: age of **technology** explosion.

- **Modern networking:** the world is going 100GB (100 times faster) with its Internet-2s, fiber optic channels, parallel transfer procedures, using modern https, sftp and other protocols.
- **Modern platforms:** high performance storage, archival and computing on massive, distributed, parallel, cloud computing environments such as **HIVE**, Galaxy, Seven Bridges, Nexus, many others ...
- **E-doc:** tens if not hundreds of solutions for secure document workflows, electronic signature systems, processual and **smart contract** systems, etc ...
- **Security:** novel paradigms of encryption, **blockchain**, distributed data lakes, private/public key systems, **hyper-ledger**, etc ...
- **Bioinformatics:** innovative evolutionary algorithmics, artificial intelligence, stochastic modeling, natural language processing, HIVE algebraic attractors, modeling and simulations, data standardization protocols, **honeycomb typing**, data janitorial services ...

A perfect setup: we have the Lego pieces, all we need is the builder.

Development of **technology** explosion.

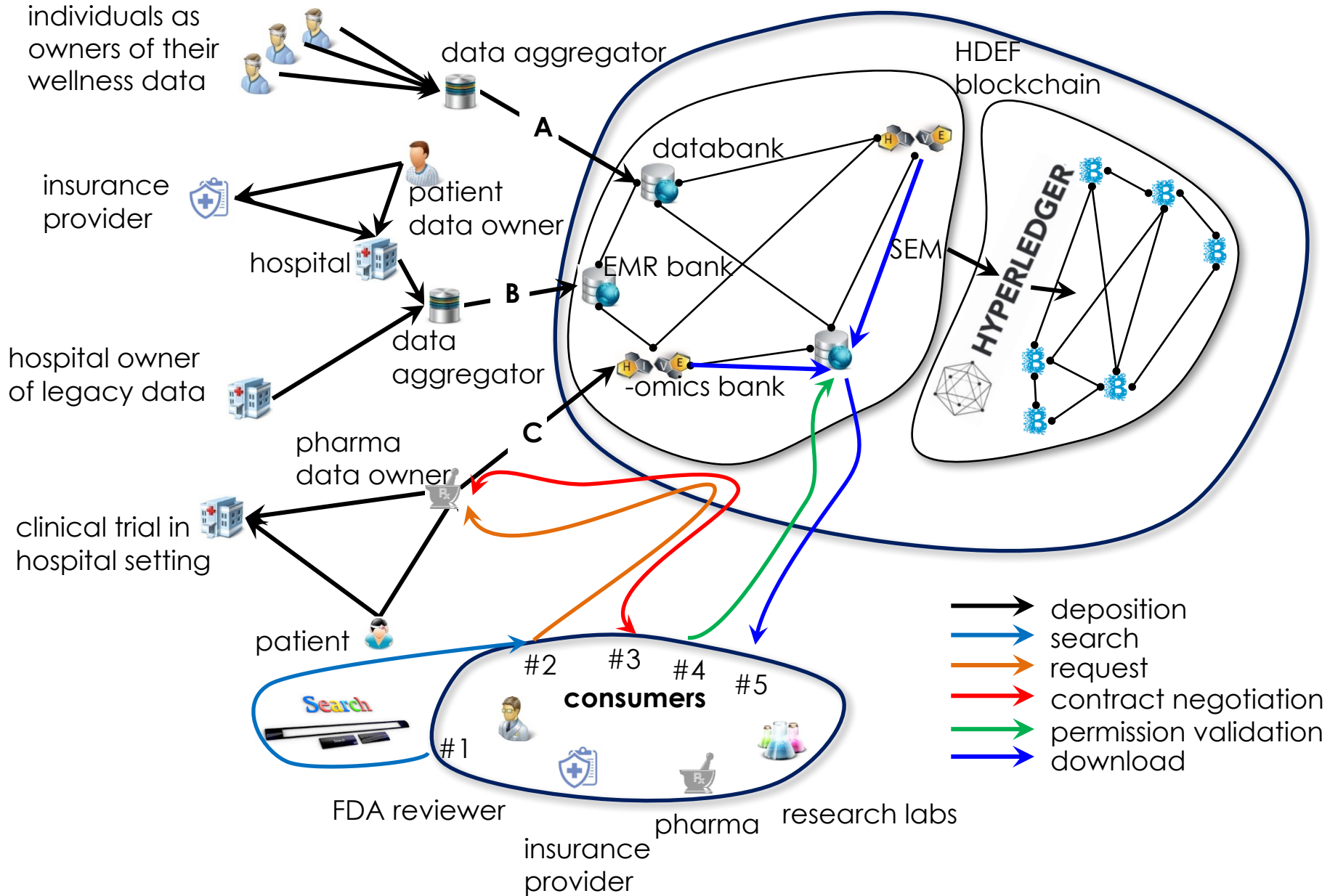
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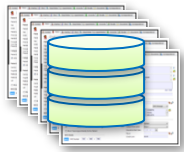
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HDEF: what is required

- **security:** to ensure protection of private, proprietary data
- **speed of transfer:** to ensure fast and efficient on demand transfer
- **ease of electronic document flow:** to facilitate administrative and legal processes
- **transaction auditability:** to enable tracing and logging every single transaction
- **horizontal scalability:** to enable big, continuous, heterogeneous data
- **vertical scalability:** to enable expansion of features with new data science services

Big picture







clinical records

Contact Patient Charting Perio Visual Notes Appointments Accounts Recalls Documents Correspondence

Patient Information

- Patient Details


Patient Code: 00673 


Sex: Female 


DOB: 11 / 10 / 1978 32 yrs 2 mths

Patient Joined: 24 / 09 / 2009


Previous Name:


Marital Status: Married 

Occupation: Business Director 

How Patient Found Us: Recommendation 

- Category/Status


Patient Group: PRIVATE 


Active 


- Patient Care

Dentist: Smith Dr Michael

Hygienist:


Referred By: 00222 Dr Dermot O'Flynn 

Referred To: 


GP: 00017 Mr Graeme Anderson 


Block Future Appointments for this Patient

- NHS Details

 NHS Number: 123 - 456 - 789

- Medical Details


Infectious: Hepatitis C 


Medical Alert: CHOLESTEROL HIGH BLOOD PRESSURE HEART CONDITION 


Medical History: [Add](#) | [Edit](#)

Preferred Anaesthetic:

- Correspondence


Document Recipient: 

Preferred Contact Method: SMS M 

Mailshot Categories: COSMETIC FACIAL IMPLANTS 


Unsubscribe


- Payment Information

 Default Price Schedule: Default

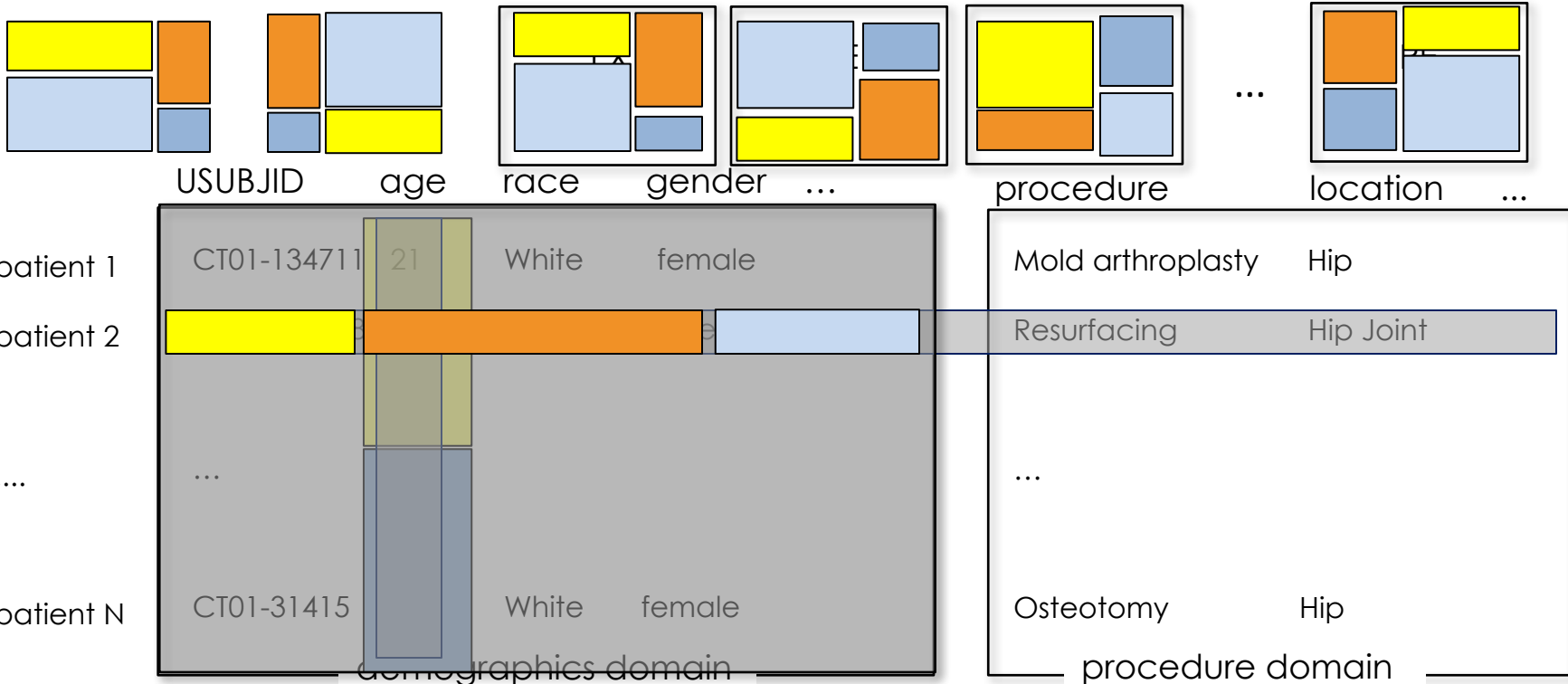
Default Price Level: Price 1

Insurance Start Date: / /

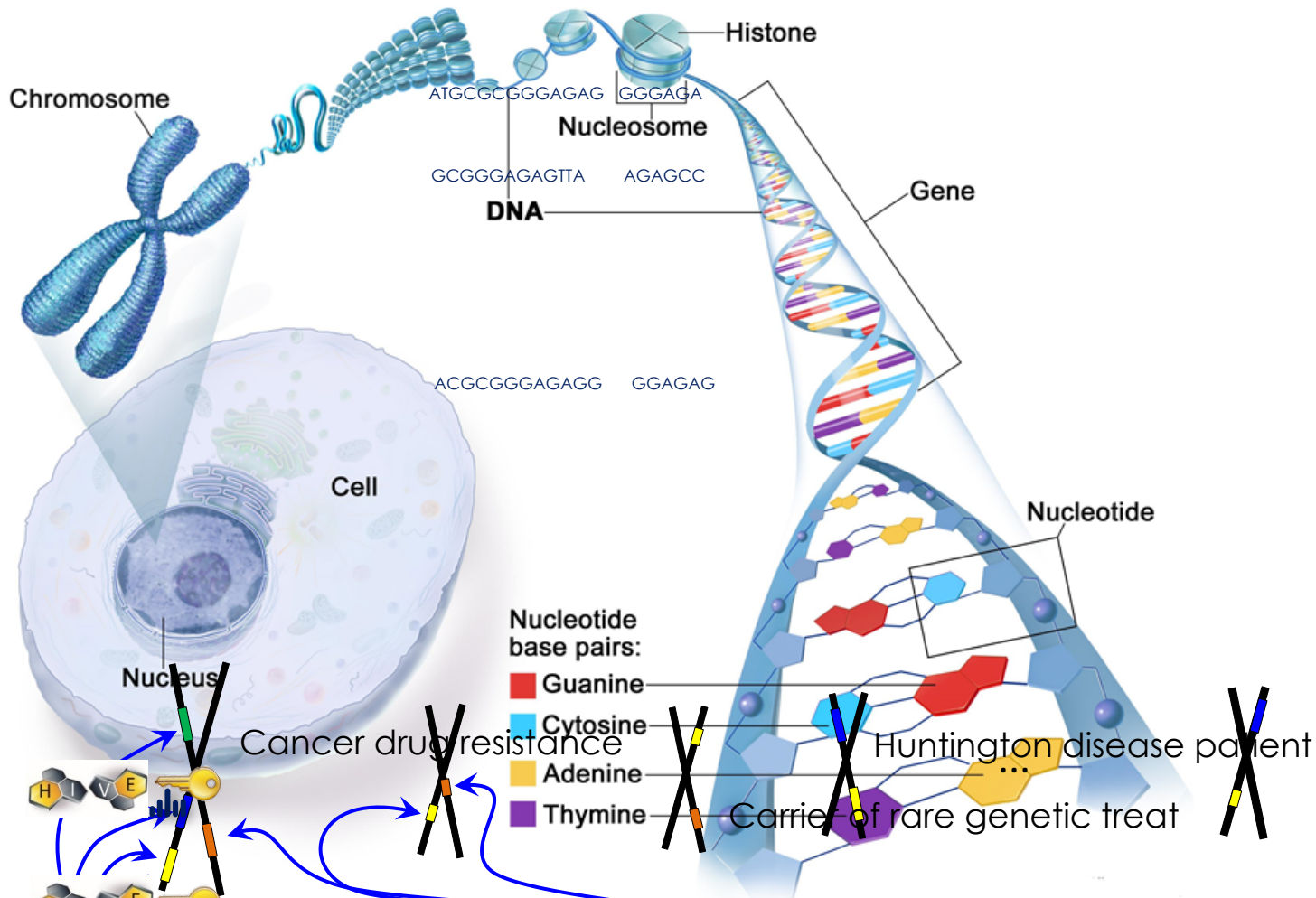
Payor: 

Credit Limit: €0.00 





DNA Structure



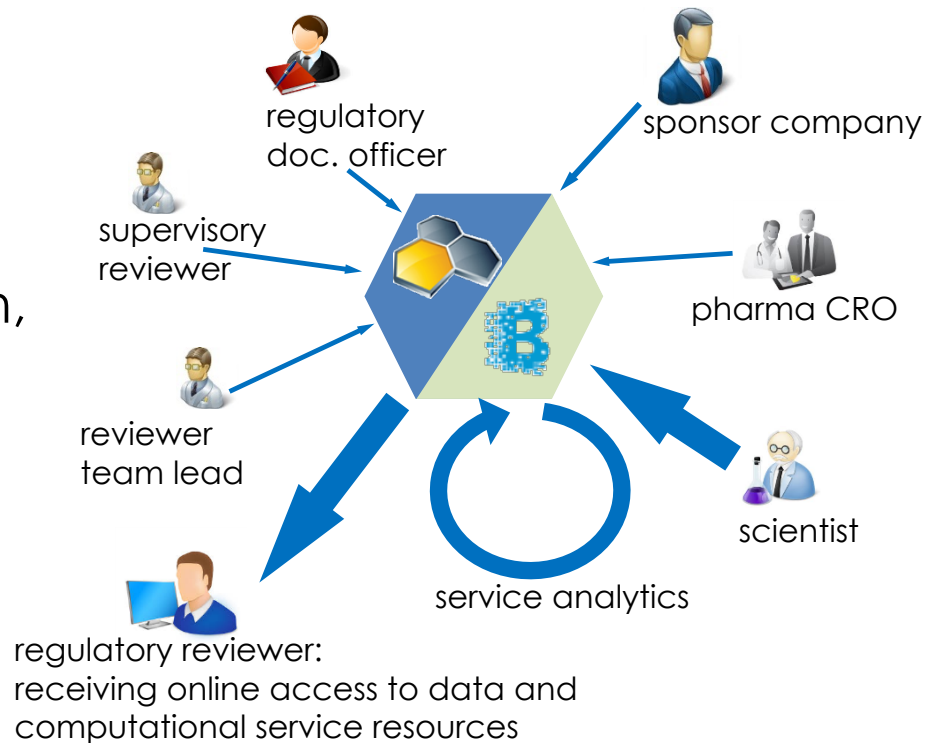
search engine

Tens of thousands of features to be extracted about patient: predictive, prognostic, diagnostic

> precision medicine lets us treat patients based on their genetic makeup: one chromosome and a single gene at a time.

Resolution: it works

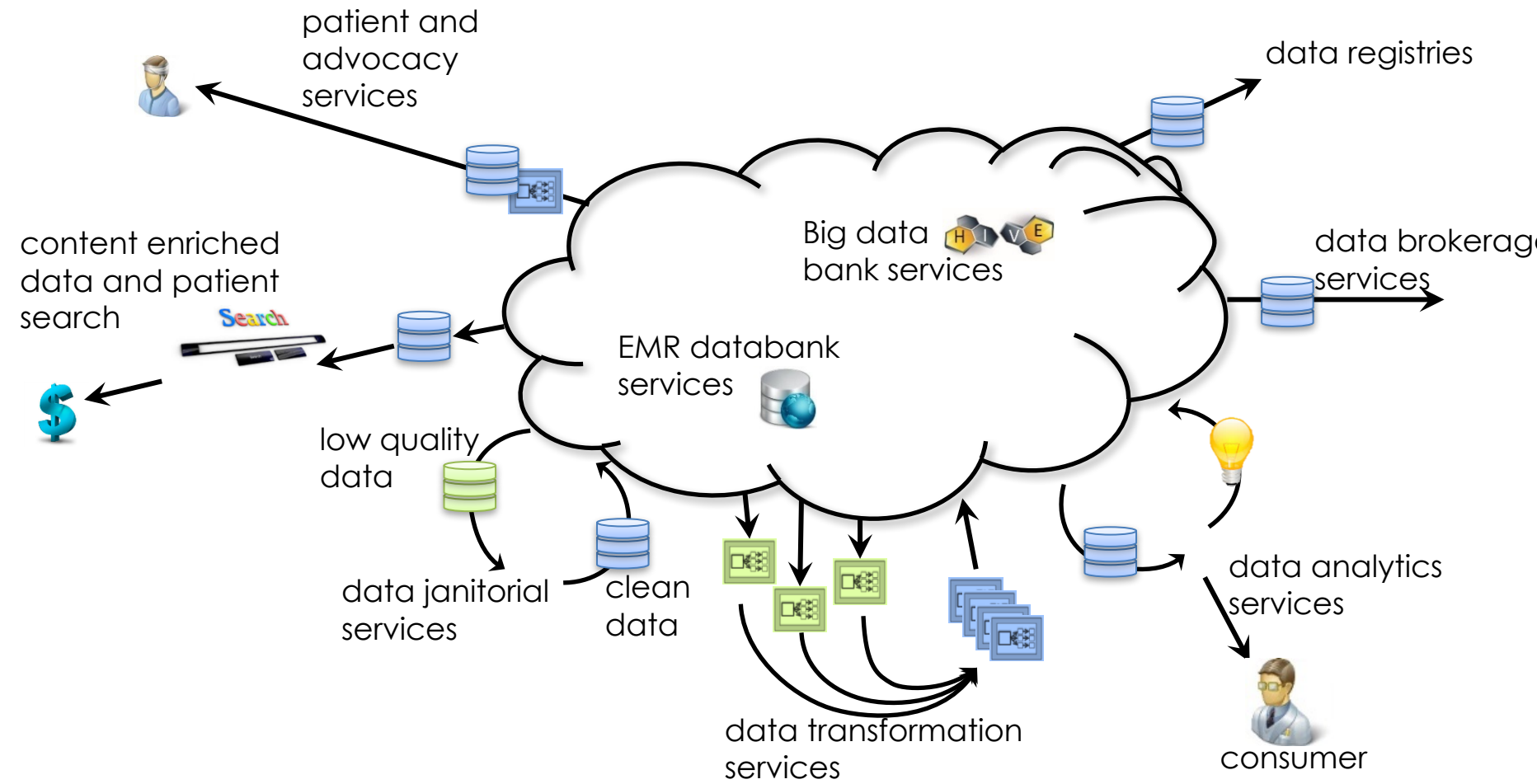
- **fast:** takes minutes to receive the data through parallel concurrent network pipes using modern protocols of download, DUA contracts, electronic signatures
- **secure:** uses novel data & process delocalization paradigms from HIVE and blockchain technology in order to ensure unbreakable, uninterpretable, heuristic distribution of information
- **provenance:** tracking of data provenance is by design enforced by policy, auditable and traceable
- **scalable:** type and size agnostic peta-scale platform optimized for large data storage, transformation, and analysis.
- **cloud compatible:** may extend to FedRAMP approved cloud and compliment the hardware with end-to-end solution



Resolution:

- technology works – welcome to 21st century
- platform is deployed and is being expanded, current participants : FDA, IBM, GWU, Harvard, Cornell, small businesses
- we can move any type of data and practically any size of data, we can move and host not just data, but processes also
- and we did it based on open source codebase: anyone can participate
- we can do more with this - in-silico, virtual cohort, pragmatic and continuous trials, harmonization, standardization, data janitorial and compounding services, data brokership and derivation services
- roundtable on HDEF is to be held this Oct 26 with a large conference and release to follow up early next year

Poetic culmination: what else we can do ?



Inspiring afterthoughts ?

- liberation of patient data through patient ownership of data
- enabling legacy data reuse and value recovery
- optimization and then transformation of the regulatory review process entirely
- direct patient to registry, patient to doctor, patient to scientist relations
- ...
- the next bullets are limited only by your imagination
- ...
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