

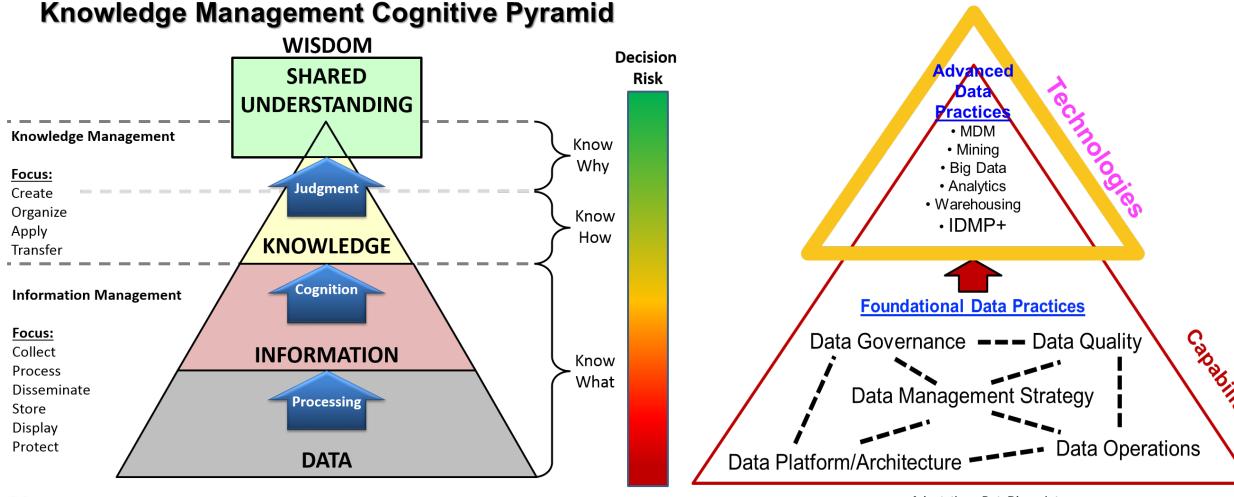
<u>GInAS</u>

Regulatory Landscape:

IDMP: Data in the Regulatory Environment

Vada A. Perkins Managing Principal

Regulation is a Business and <u>Data-Driven</u> Environment

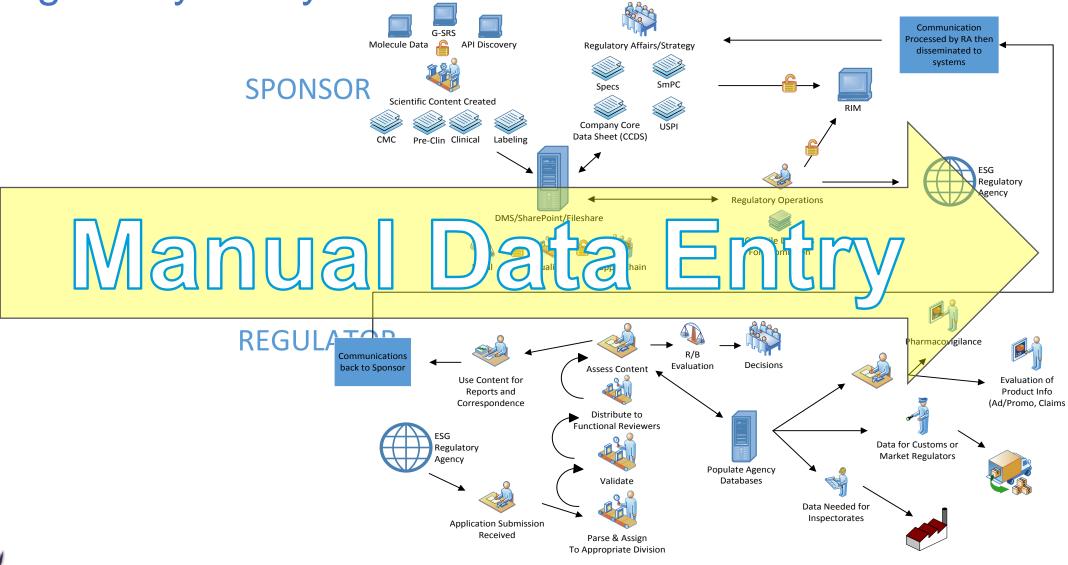


Adaptation of the DIKW Pyramid by US Army Knowledge Managers



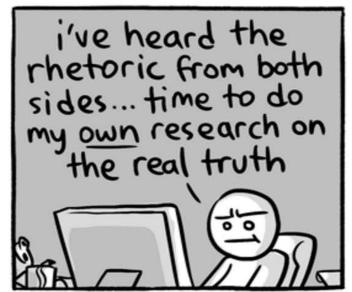
Adaptation: DataBlueprint

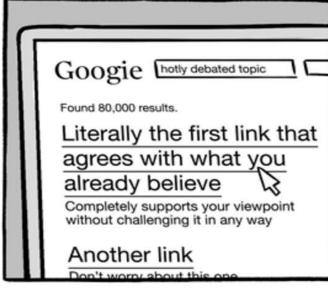
Regulatory Lifecycle





Cognitive Bias







Gambler's Fallacy Post-Purchase Rationalization

Observational Selection Bias

Status-Quo Bias



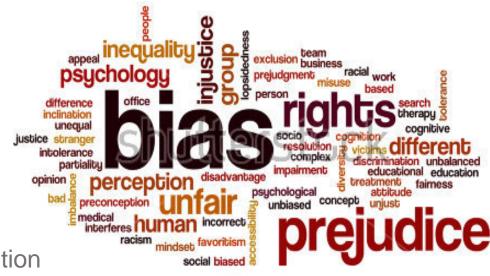
Cognitive Bias

Cognitive Bias Drivers:

- Information overload
- Lack of meaning
- Need to act fast
- Remember/Recall:
 - Generalization vs. Specifics

Downside:

- We don't see everything
 - Filter useful and important information
- Illusions in context
 - Imagine details per assumptions
 - Construct meaning and stories
- Flaws in quick decision making



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Digital Amnesia (Google Effect)

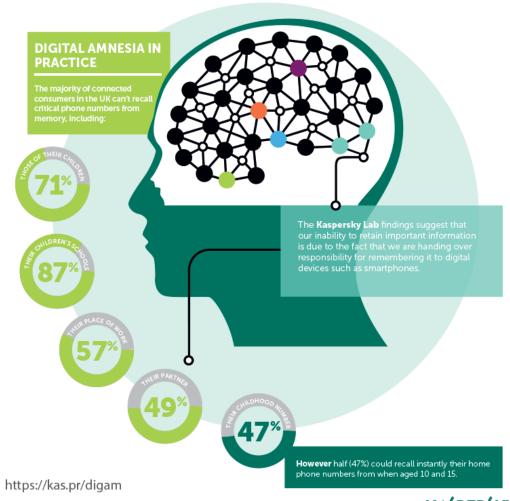
The experience of forgetting information that you trust a digital device to store and remember for you

Coined by Kaspersky Lab (2015 survey) 91% of those surveyed (n=1000) utilize the Internet as an online extension of their brain

44% stated smartphone serves as their memory



Digital Amnesia in Practice



The Majority of (UK) Connected Consumers:

- Cannot recall critical phone numbers including:
 - 71% Those of their children
 - 87% Their Children's Schools
 - ▶ 57% Their Place of Work
 - ▶ 49% Their Partner
 - ▶ 47% Their Childhood Phone number
 - Generalization vs. Specifics
- However almost half (47%) could instantly recall their home phone numbers when aged between 10 and 15 Years...





Regulatory Divergence

- Impediment to regional and global development and availability
- Leads to redundancy in studies, testing, analysis, regulatory assessment/review
- Different regulations (global)
- Different interpretation can result in different responses
- Regulatory Authorities
 - Global safety, efficacy, surveillance initiatives
 - Regulations and systems differ which impede information exchange both regionally and globally



"Data Revolution"

- ► Transition by international regulators/Industry to structured content/structured authoring
 - Supports more efficient and effective regulatory review
 - Supports regulatory science initiatives
 - **Pharmacovigilance** (signal detection)
 - Quality metrics
 - Risk based inspection scheduling
 - Mitigate drug shortages
 - Real World Data/Evidence
 - In support of benefit/risk assessment

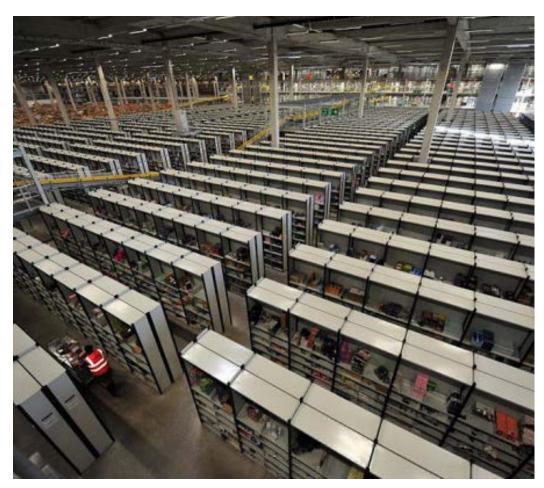




Document Control/Records Management



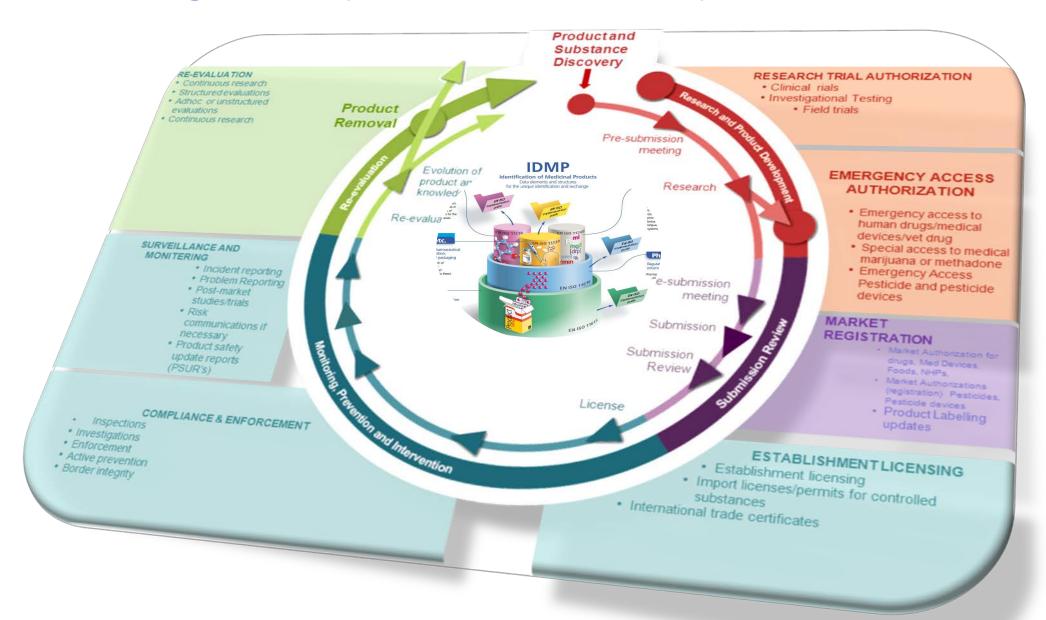
Paper



Electronic



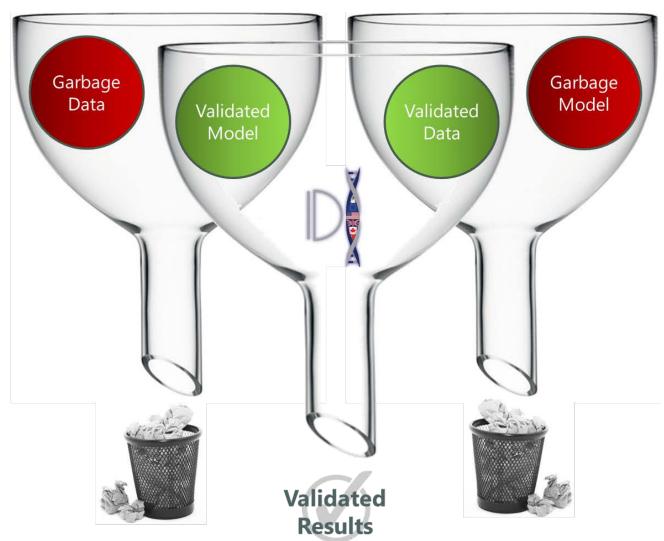
Global Regulatory Product Lifecycle





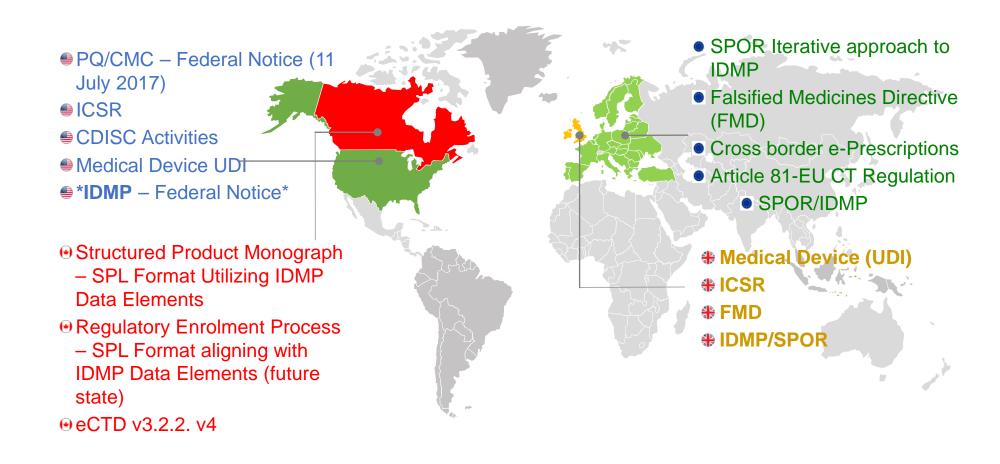
Garbage In – Garbage Out





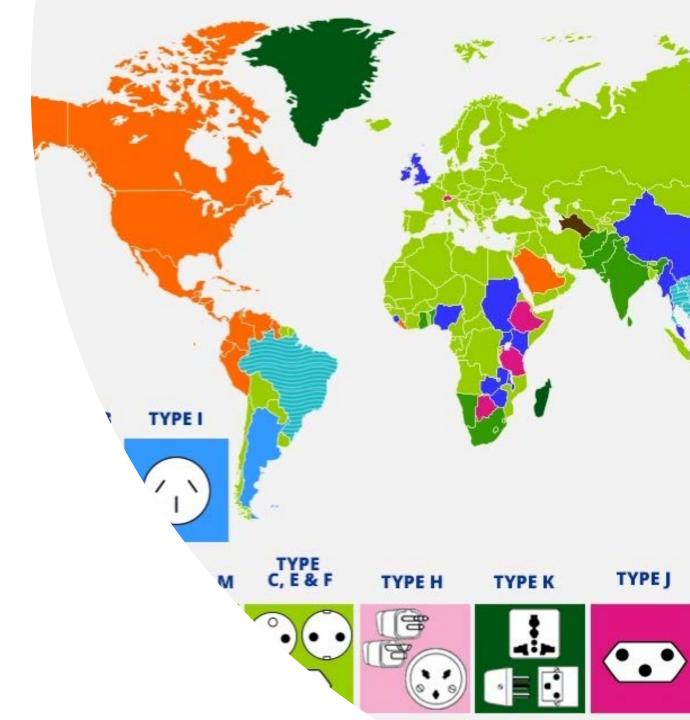


Regulatory World View: Standards Adoption



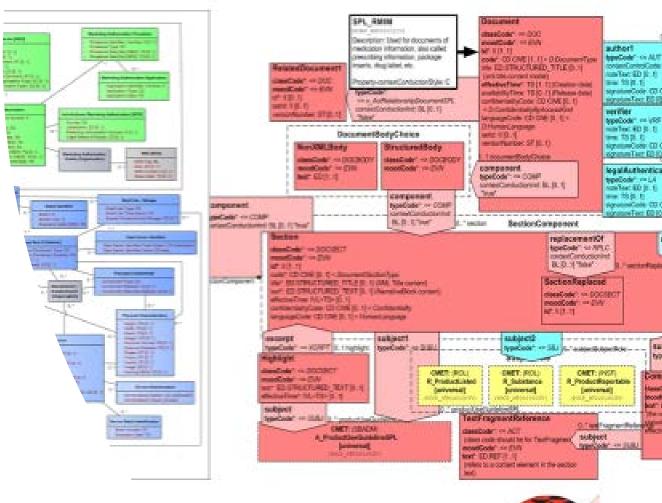


Incompatibility





Standards Development: Content & Message



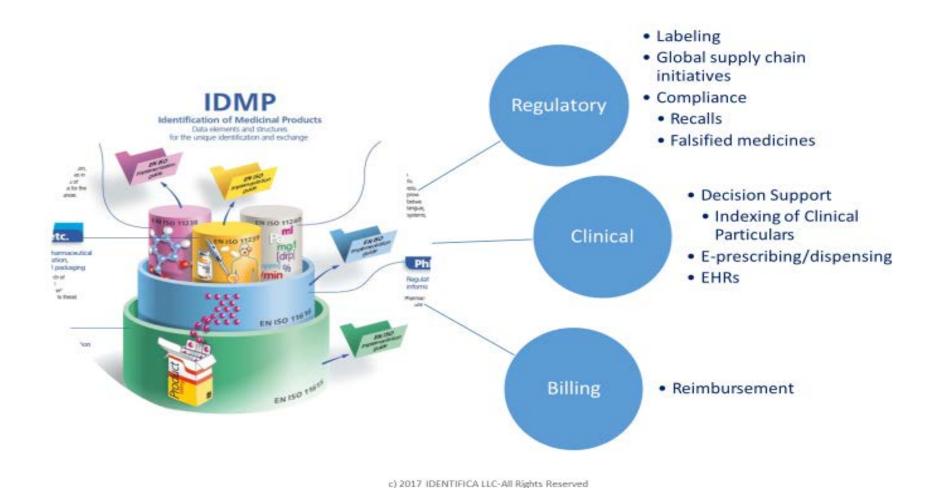




Messaging



Utilization: Global Medicinal Product Identification





Data Integrity and Compliance with cGMP

- ►FDA has increasingly observed cGMP violations involving data integrity during cGMP inspections
- ► Data integrity-related cGMP violations have led to numerous regulatory actions:
 - ► Warning letters
 - ▶ Import alerts
 - ► Consent decrees



Quality Metrics

- ▶Quality metrics-used across the pharmaceutical industry
 - ► Monitor quality control systems and processes
 - ► Continuous improvement efforts in drug manufacturing
- ►Metrics can also be used by regulators for the following:
 - ► Compliance and inspection policies and practices
 - ▶ Risk-based inspection scheduling of drug manufacturers
 - ▶ Improve the ability to predict and possibly mitigate future drug shortages;
 - ► Encourage Industry to implement state-of-the-art, innovative quality management systems for pharmaceutical manufacturing



Real World Data for Regulatory Decision Making

- ▶ RWD should be collected with controls to limit bias...
- May provide information wider patient population than a more traditional clinical trial,
 - and thus provide information that cannot be obtained through a traditional clinical trial alone
- ► Retrospective analysis of RWD may have some inherent bias that could limit its value as RWE

Standardized file format and data structure, and adhere to a recognized common data model as data as presented in clinical trials

Real World Data for Regulatory Decision Making

- ► Collection and interpretation:
 - ▶ Pre-defined common set of data elements,
 - ► Common definitional framework (i.e., data dictionary)
- Supplement existing data through linkage with other data sources (e.g., EHRs) to provide additional or confirmatory data
 - ▶ will also be considered when assessing relevance of the RWD
- Use and recognition of the RWD source regionally, nationally and/or internationally
- Validation rules to evaluate the RWD source per regulatory criteria

RWD: Data Relevance & Reliability

►Relevance

- ► Adequately addresses applicable regulatory requirement(s) for its intended purpose
- ► Generate sufficient evidence to support effective and efficient regulatory decision making

▶ Reliability

- ► Data accrual
- **▶Data** adequacy
- ► Data assurance
 - **▶** Data quality and integrity
 - **▶** Minimize bias



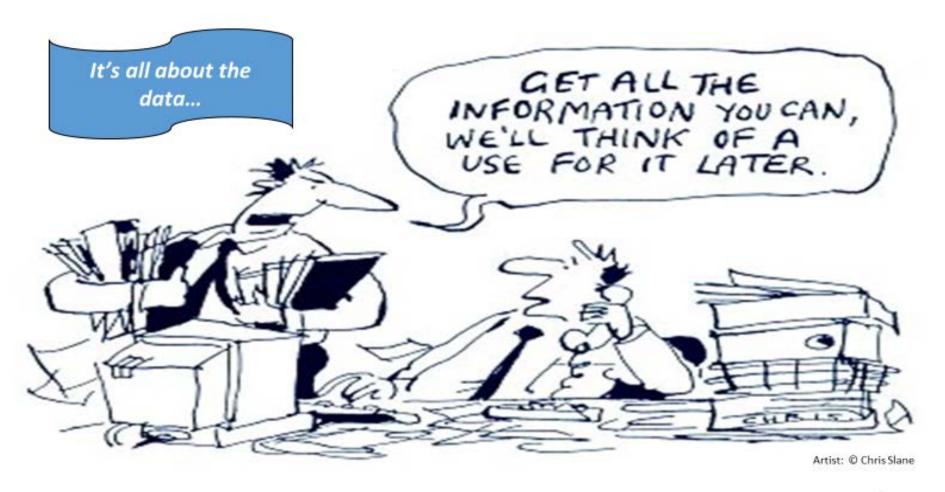
Regulatory Convergence

Process whereby the regulatory requirements across countries or regions become aligned (**common**) over time as a result of the gradual adoption of:

- Internationally recognized technical guidance documents,
- Standards,
- and Best Practices



In Summary...





Questions / Discussion / Contact

Managing Principal





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