台灣未來生技發展的機會

Future Opportunities for Taiwan's Biotech Development

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National Taiwan University

Strength of Taiwan in Biotech Development

- **Representative Population** in East Asia
- Improved Cross-Strait Relationship
- Competitive, Strong **R&D Activities** and **Manufacturing Capabilities** in Computer Sci., Electric Engineering, Biotech, Clinical Medicine, *etc.*
- **Integrated** Government-Industry-Academia-Hospital, **Transparent Regulatory Environment**
- Excellent **Health Care System,** National Health Insurance: $\geq$ **99%**
- **Center of Excellence for Clinical Trials** in East Asia
  R&D for Pfizer, GSK, BI, MSD, Novartis, Eli Lilly, Roche, AZ, Bayer, etc.
- **Government's Investment** and **Support**

2015 Taiwan Total Ranking # 25

1. Productivity # 23
2. IP # 29
3. Intensity # 31
4. Enterprise Support # 8
5. Education/Workforce # 33
6. Foundation # 12
7. Policy & Stability # 24

SEVEN YEARS OF BIOTECH TRACKING BY RANK

Our growing database reveals ongoing competition at many levels

Taiwan's Ranking:

2012 # 21

2013 # 26

2014 # 17

2015 # 25

Average # 22.3

change since last year (neg. values = improvement)

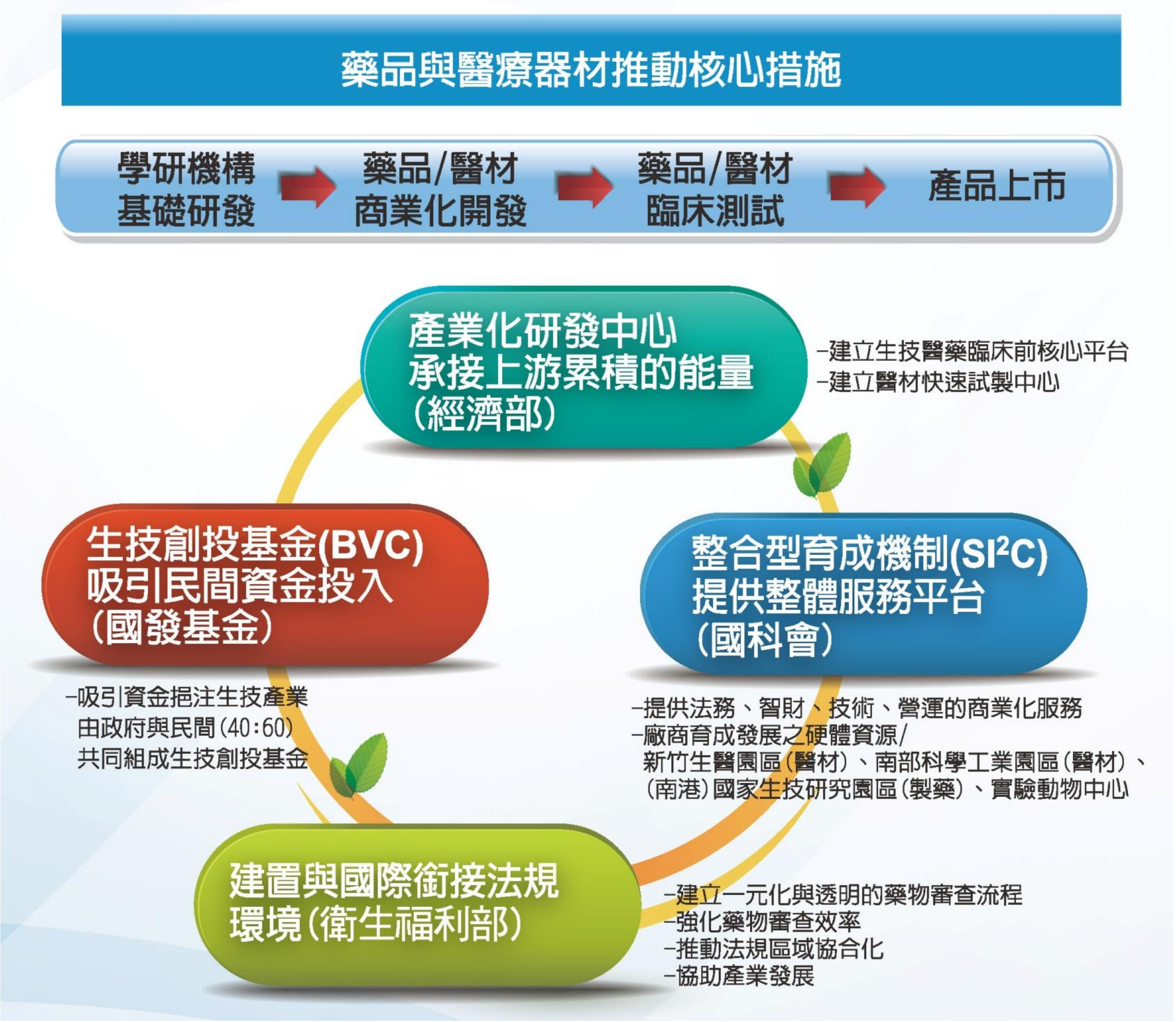
COUNTRY	2009	2010	2011	2012	2013	2014	2015	AVG.	±
UNITED STATES	1	1	1	1	1	1	1	1.0	0
DENMARK	3	5	2	2	2	3	2	2.7	-1
NEW ZEALAND	7	18	18	9	10	8	3	10.4	-5
AUSTRALIA	10	17	5	10	7	4	4	8.1	0
SINGAPORE	2	2	8	3	5	2	5	3.9	3
FINLAND	8	6	7	4	4	7	6	6.0	-1
SWITZERLAND	6	10	6	6	3	6	7	6.3	1
SWEDEN	4	4	3	5	6	5	8	5.0	3
UNITED KINGDOM	12	14	9	11	9	9	9	10.4	0
CANADA	11	3	4	7	8	11	10	7.7	-1
HONG KONG			17	13	20	12	11	14.6	-1
GERMANY	16	16	16	16	14	13	12	14.7	-1
IRELAND	14	13	14	8	11	16	13	12.7	-3
NETHERLANDS	19	12	12	17	12	14	14	14.3	0
FRANCE	18	8	10	12	13	15	15	13.0	0
JAPAN	13	9	11	18	18	18	16	14.7	-2
NORWAY	17	21	21	19	22	19	17	19.4	-2
ISRAEL	5	7	13	14	15	22	18	13.4	-4
AUSTRIA	21	20	20	20	17	20	19	19.6	-1
LUXEMBOURG		25	29	25	19	10	20	21.3	10
BELGIUM	20	15	15	15	16	21	21	17.6	0
QATAR					42	25	22	29.7	-3
SOUTH KOREA	15	19	19	22	24	23	23	20.7	0
ICELAND	9	11	22	23	23	24	24	19.4	0
TAIWAN,				21	26	17	25	22.3	8

臺灣生技產業成功要素

- **善用臺灣臨床研究環境**
  - 世界大廠輝瑞、諾華、GSK、MSD、Bayer、Boehringer Ingelheim等與臺大醫院等卓越臨床中心合作，建置區域性或世界級臨床研究中心
  - 臺灣醫界精英在肺癌、肝炎等領域，居世界領導地位，藥品臨床試驗整體表現居亞太領先群
- **善用健保與醫療服務經驗**
  - 經濟學人、洛桑管理學院等對臺灣健保高度評價，優質高效之醫療服務足為新興國家楷模，管理服務模式具輸出潛能
- **運用ICT與精密機械能力，配合醫療器材需求，發揮綜效**
  - 百略及必翔等醫材廠商在血壓計、代步車之國際市佔率領先，近期SwissRay 併購案則為台商掌握整合技術規格、品牌、通路之切入良機
- **面向國際與兩岸市場**
  - 藉助兩岸合作、國際大廠管道發揮研發效益，應是未來發展方向

✓ **解決問題，發揮潛力**
- 上游研發尚佳，已累積相當能量，需加強產業化能力（「寶劍出鞘」）
- 臺灣是國際藥廠進入大陸的灘頭堡（智財保護、兩岸醫藥合作協議）
- 臺灣股市生技股近一年明顯增溫

臺灣生技產業起飛行動方案



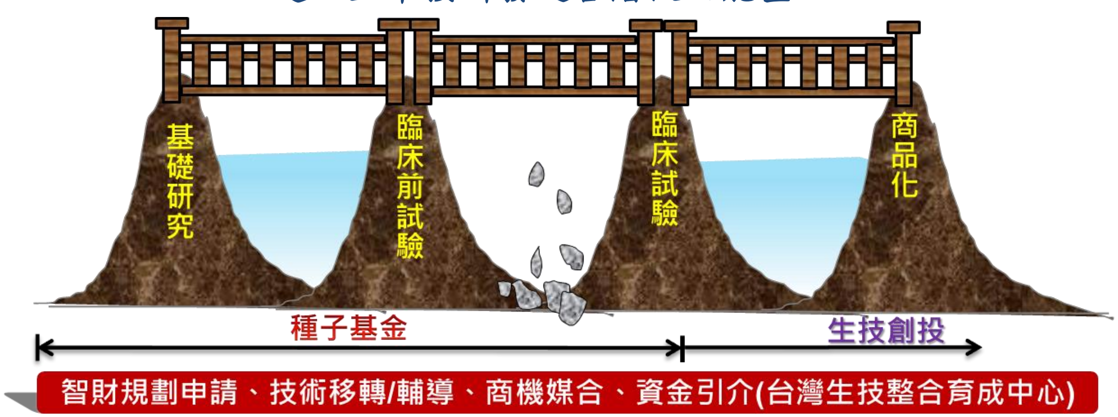
生技整合育成中心

(Supra Integration and Incubation Center, SI^2C)

SI^2C 以 Branding Taiwan 為目標，針對藥品、醫材執行四大主軸工作：

1. 評估、建構及串連產業價值鏈研發能力、平台及核心設施，讓有潛力的**新藥**與**醫材**能順利往價值鏈後端推動，增加其成功的機會，使台灣在特選的疾病及產品種類居亞太領先及領導的地位；
2. 建立完整的選題機制，主動積極發掘與篩選國內外具商業化潛力及研發可行之案源，進行輔導與協助；
3. 成立種子基金，支持前期研發計畫，以與國內創投後期研發的投資接軌；
4. 構思成立新的園區模式，使生醫園區成為研發的**One-stop shop**，協助新興業者與學術界研發團隊在需要時能適時運用其所建構的平台與核心設施，並連結政府相關單位窗口及新興公司資金協助及整合服務。

建立並串接研發鏈各階段之能量



資料來源:國科會

Supra Integration and Incubation Center (SI2C)

Connection of the value chain

Identification of potential projects

Securing talents for biomedical technology

Build-up Taiwan biomedical ecosystem

生技聚落規劃

- **醫療器材為主**
(醫療器材＋ICT)

新竹生物醫學園區
(竹北)

新竹科學工業園區
(新竹、竹南)

中部科學工業園區
(台中、后里、二林、虎尾、南投)

臺灣蘭花生物科技園區
(台南)

南部科學工業園區
(台南、高雄園區)

- 醫療器材為主
(骨科、牙科材料)

南港生物科技園區

南港國家生技研究園區
(中研院統籌)

- **新藥研發為主**

園區包括：生醫轉譯研究中心、核心主題研究中心、生物資訊中心、育成中心、國家實驗動物中心、生物技術開發中心、食品藥物管理局
(預計105年10月15日前竣工)

屏東農業生物科技園區

2015年「生產力4.0科技發展會議」

工業 1.0

生產機械化時代

珍妮紡紗機的發明、瓦特改良蒸汽機，英國運用蒸汽動力讓生產從手工邁入機械時代

工業 2.0

大量生產年代

1908年福特汽車創辦人Henry Ford以流水線裝配方式，改革生產流程，大幅降低生產成本

工業 3.0

生產自動化普及

1975年德國和日本企業，以電子及網路通訊技術，將讓運算控制功能分布到系統各端，提高整體效能

工業 4.0 智慧製造

德國提倡以物聯網、無線通訊為基礎，建構Cyber-Physical Systems(CPS)系統

複雜度

18世紀末　20世紀初　20世紀/70年代　今天　時間軸

重大發展課題研析

解決台灣經濟和生活課題

- **解決老年化和少子化，致工作人力及生產力下降**
- **製造業外流(技術與人才)、附加價率下滑**
- **中小製造廠商實體數位化能力不足，將受衝擊**

高質(值)精微化

- 價值性(密度):精微製造、精密量測、監控和遠程診斷服務、中央監控系統
- 不可模仿性(深度):智慧控制器與關鍵元件技術研發
- 技術延伸性(廣度):應用IOT、Big Data和雲端等技術，提高產品附加價值

敏捷數位化

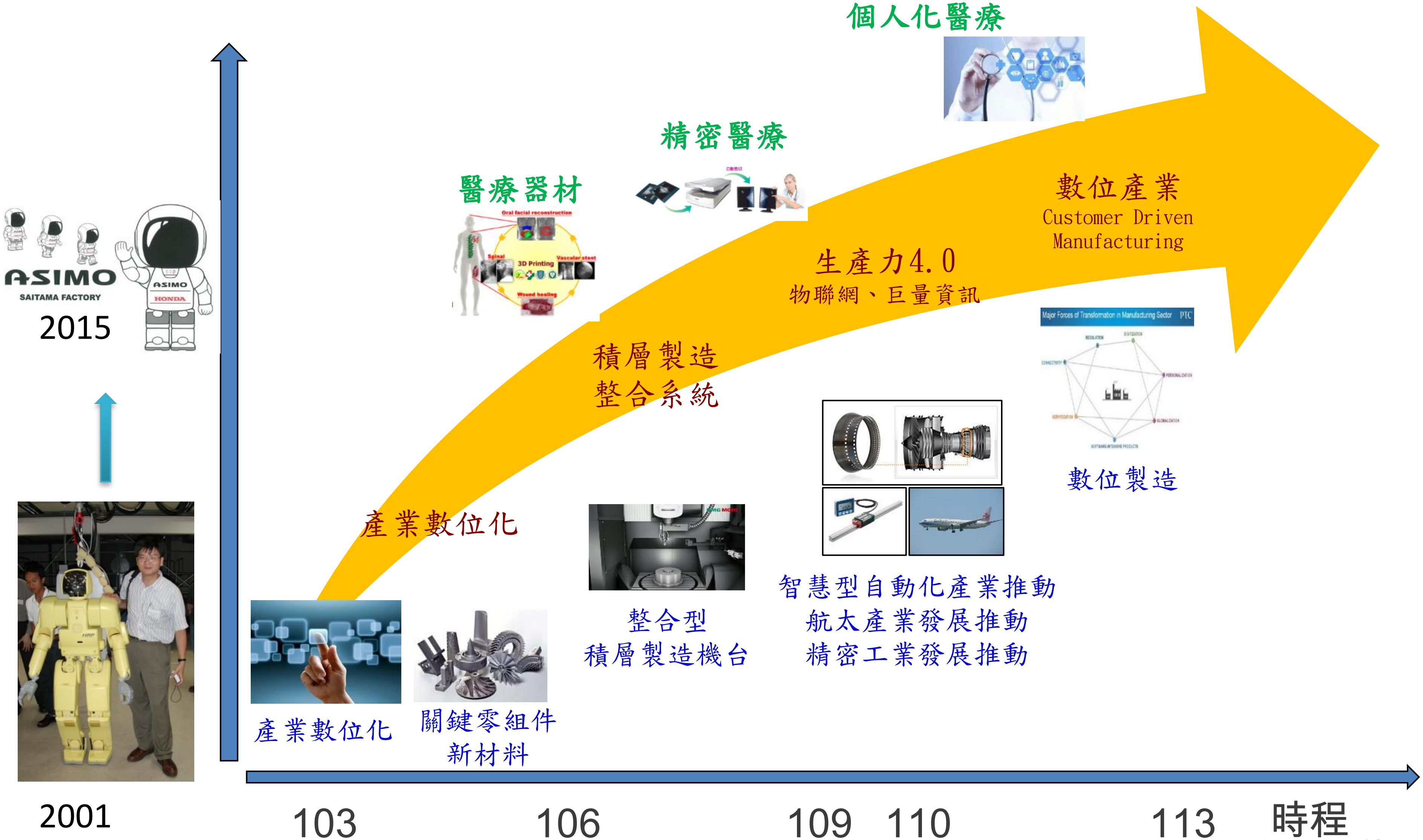
- 系統:協助中小企業實體製造數位化，並建立CPS系統
- 平台:智慧生產平台、整線生產平台(跨產業鏈)研發
- 整廠整線設計:取得整線生產系統、智慧工廠等，具高值化輸出技術，在先進製造等領域產生規模效應。

服務人性化

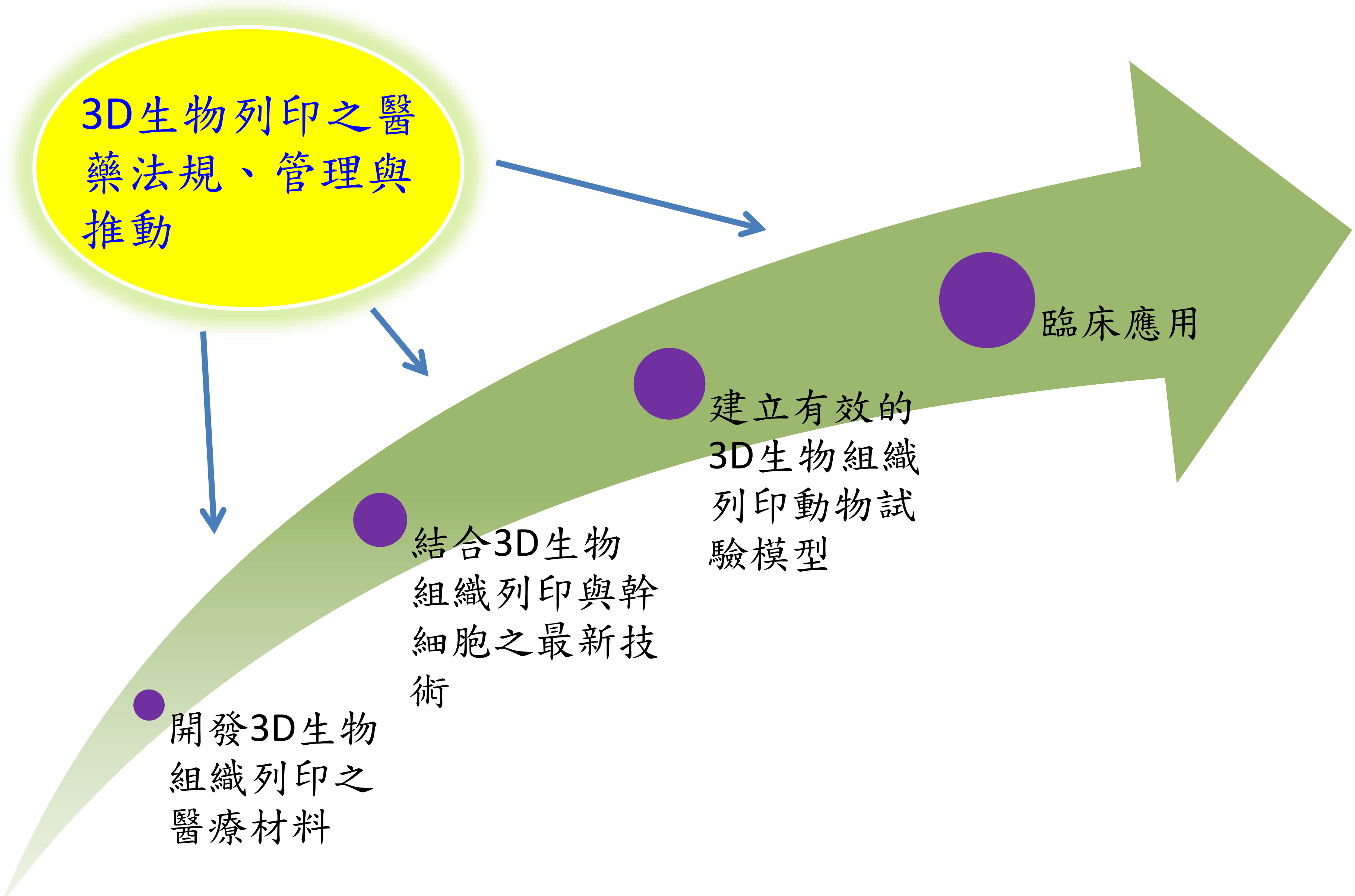
- 人機協同:設計與製造一體化、遠端控管與排程
- 服務導向:個人化服務設計、一指下單生產模式
- 創新應用:達成產業結構轉型，提升中小企業數位製造等創新技術

政策依據：2015年「生產力4.0科技發展會議」

積層製造 (106-109、110-113年)



衛福部 & 科技部工作規劃


3D生物列印之醫藥法規、管理與推動
開發3D生物組織列印之醫療材料
結合3D生物組織列印與幹細胞之最新技術
建立有效的3D生物組織列印動物試驗模型
臨床應用

幹細胞跨領域及再生醫學應用

- 奈米生醫材料: 細胞分化及細胞毒性測試
- 生物反應器與組織工程
  1. 生物反應器(Bioreactor):幹細胞之標準化量產
  2. 組織工程:人工器官(Artificial Organs)
- 幹細胞治療與再生醫學應用
  1. 神經退化疾病與神經損傷 (Neural stem cells)
  2. 軟骨修復與再生 (Chondroblasts and 3D reconstruction)
  3. 血液腫瘤之細胞療法 (Hemopoietic stem cells)
  4. 心肌梗塞之細胞療法 (Cardiomyoblasts)
  5. 糖尿病之細胞療法 (Pancreatic islet cells)

Toward Precision Medicine:

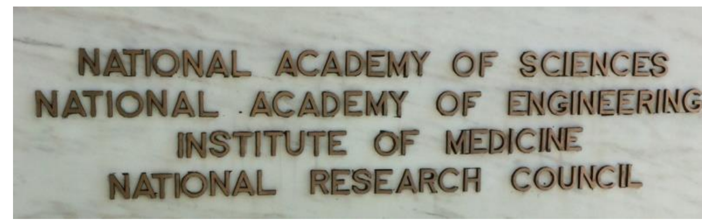
Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease

2011

Committee on A Framework for Developing a
New Taxonomy of Disease

Board on Life Sciences

Division on Earth and Life Studies



NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

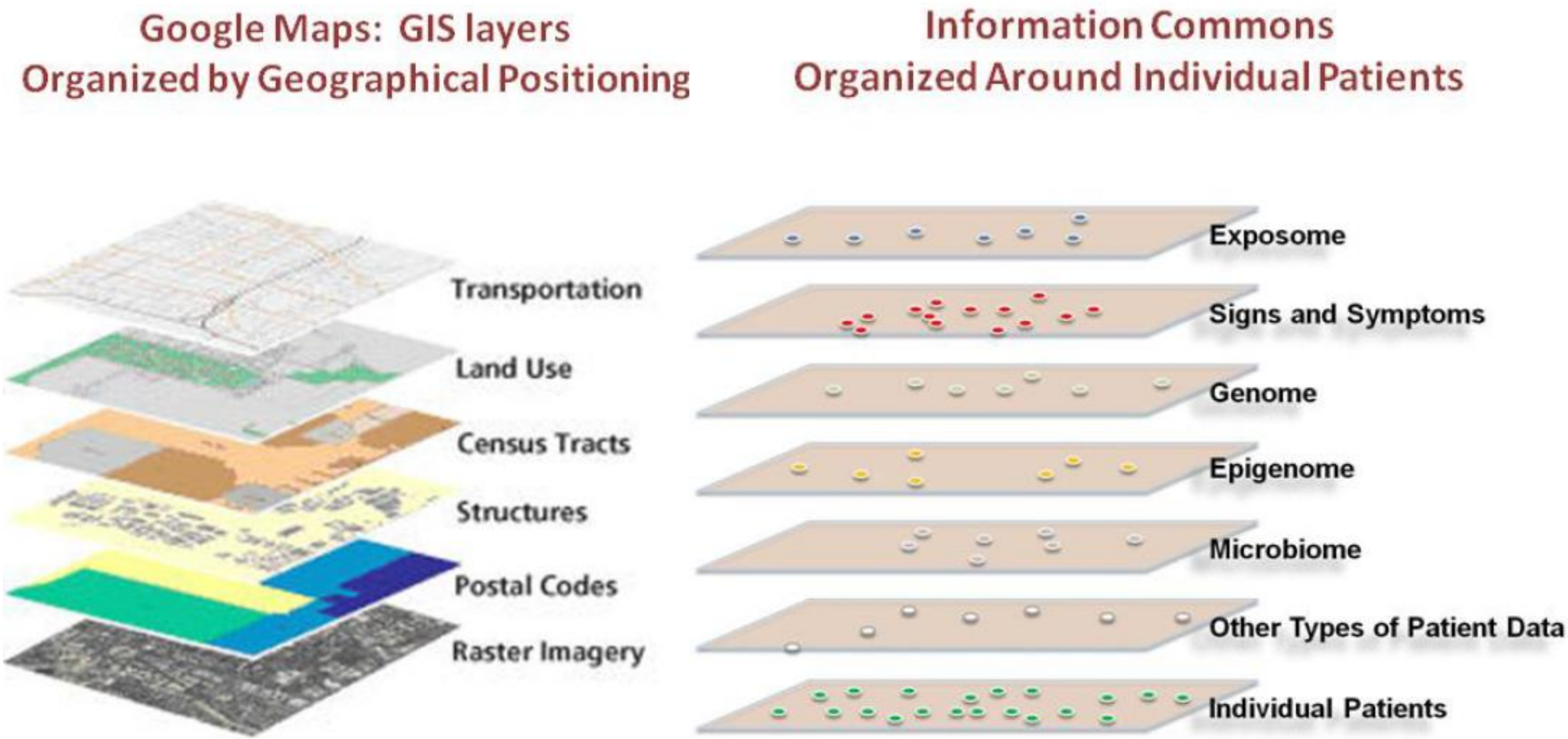


Figure 1-2: The proposed, individual-centric Information Commons (right panel) is somewhat analogous to a layered Geographical Information System (left panel). In both cases, the bottom layer defines the organization of all the overlays. However, in a GIS, any vertical line through the layers connects related snippets of information since all the layers are organized by geographical position. In contrast, data in each of the higher layers of the Information Commons will overlay on the patient layer in complex ways (e.g., patients with similar microbiomes and symptoms may have very different genome sequences). Source: FPA 2011 (left panel).

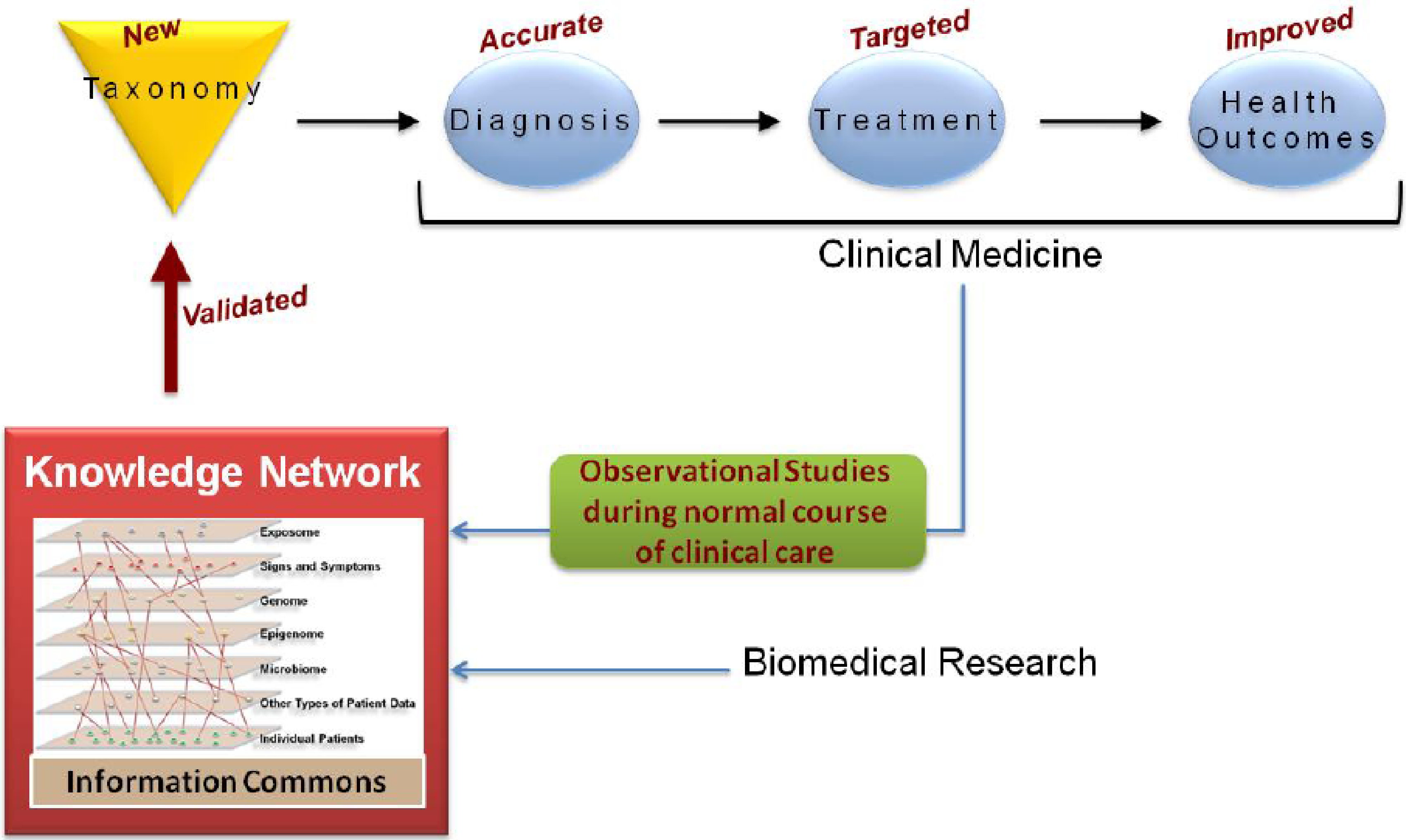


Figure 1-3: An individual-centric Information Commons, in combination with all extant biological knowledge, will inform a Knowledge Network of Disease, which will capture the exceedingly complex causal influences and pathogenic mechanisms that determine an individual's health. The Knowledge Network of Disease would allow researchers hypothesize new intralayer cluster and interlayer connections. Validated findings that emerge from the Knowledge Network, such as those which define new diseases or subtypes of diseases that are clinically relevant (e.g., which have implications for patient prognosis or therapy) would be incorporated into the New Taxonomy to improve diagnosis and treatment.

Biology Has Become a Data-Intensive Science

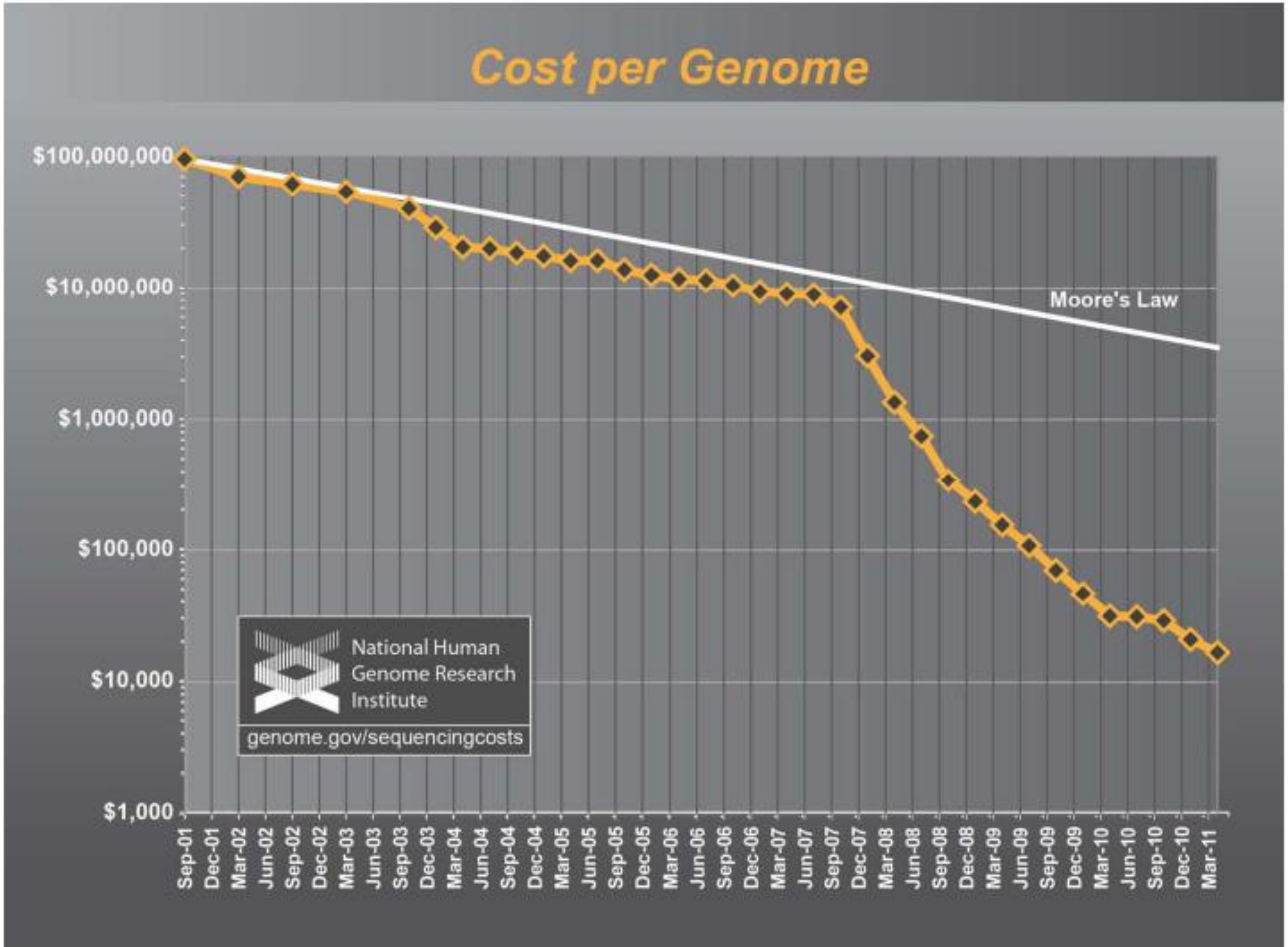


Figure 2-1: The cost of complete genome sequencing is falling faster than Moore's Law. The cost is still dropping rapidly, with a "$1000 genome" becoming a realistic target within a few years. Source: Wetterstrand 2011.

Cancer Research: Lung Cancer

at NTU Center of Genomic Medicine

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 4, 2007 VOL. 356 NO. 1

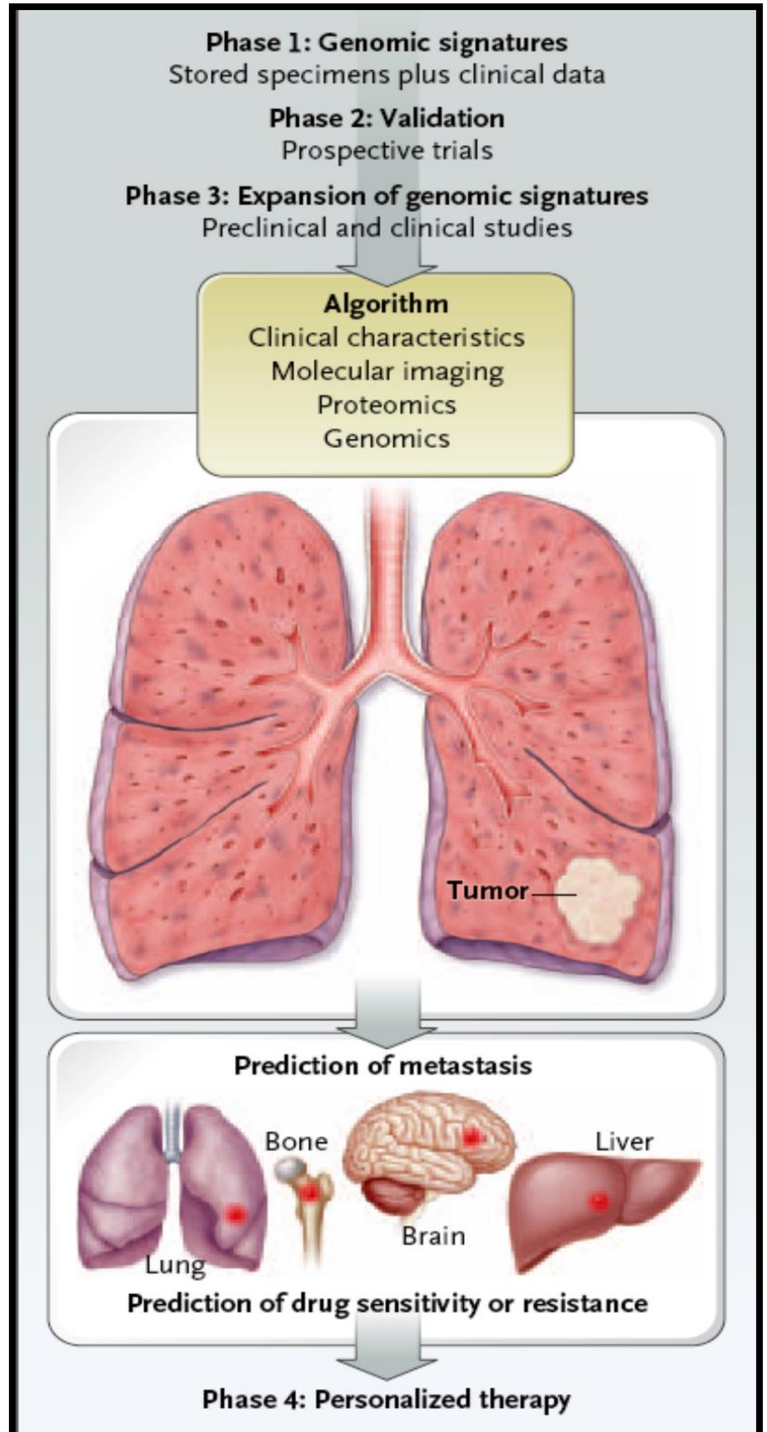
A Five-Gene Signature and Clinical Outcome in Non–Small-Cell Lung Cancer

Hsuan-Yu Chen, M.Sc., Sung-Liang Yu, Ph.D., Chun-Houh Chen, Ph.D., Gee-Chen Chang, M.D., Ph.D., Chih-Yi Chen, M.D., Ang Yuan, M.D., Ph.D., Chiou-Ling Cheng, M.Sc., Chien-Hsun Wang, M.Sc., Harn-Jing Terng, Ph.D., Shu-Fang Kao, M.Sc., Wing-Kai Chan, M.D., Han-Ni Li, M.Sc., Chun-Chi Liu, M.Sc., Sher Singh, Ph.D., Wei J. Chen, M.D., Sc.D., Jeremy J.W. Chen, Ph.D., and Pan-Chyr Yang, M.D., Ph.D.

EDITORIAL

Molecular Signatures of Lung Cancer — Toward Personalized Therapy

Roy S. Herbst, M.D., Ph.D., and Scott M. Lippman, M.D.



The Opportunity to Integrate Data-Intensive Biology with Medicine

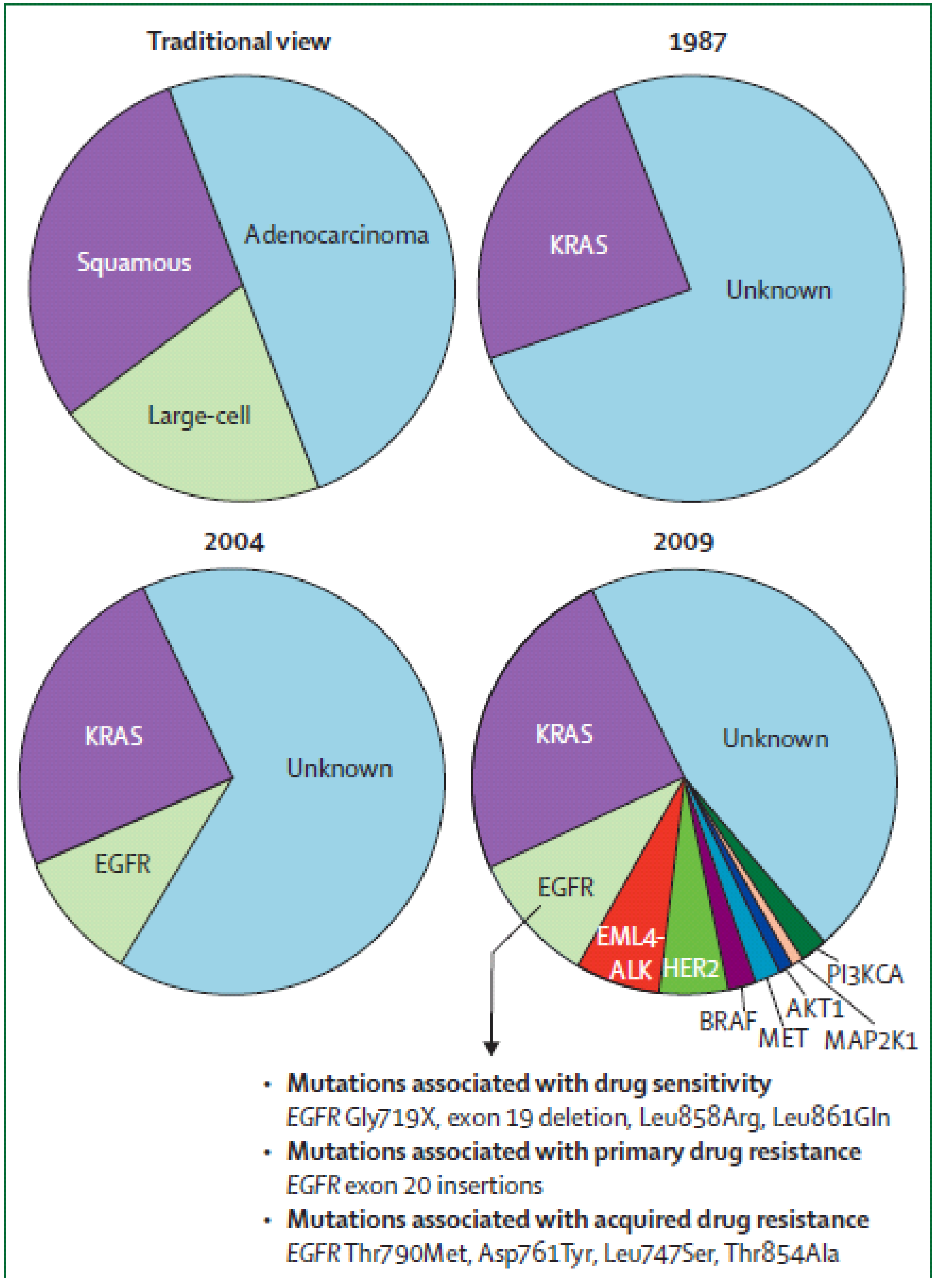
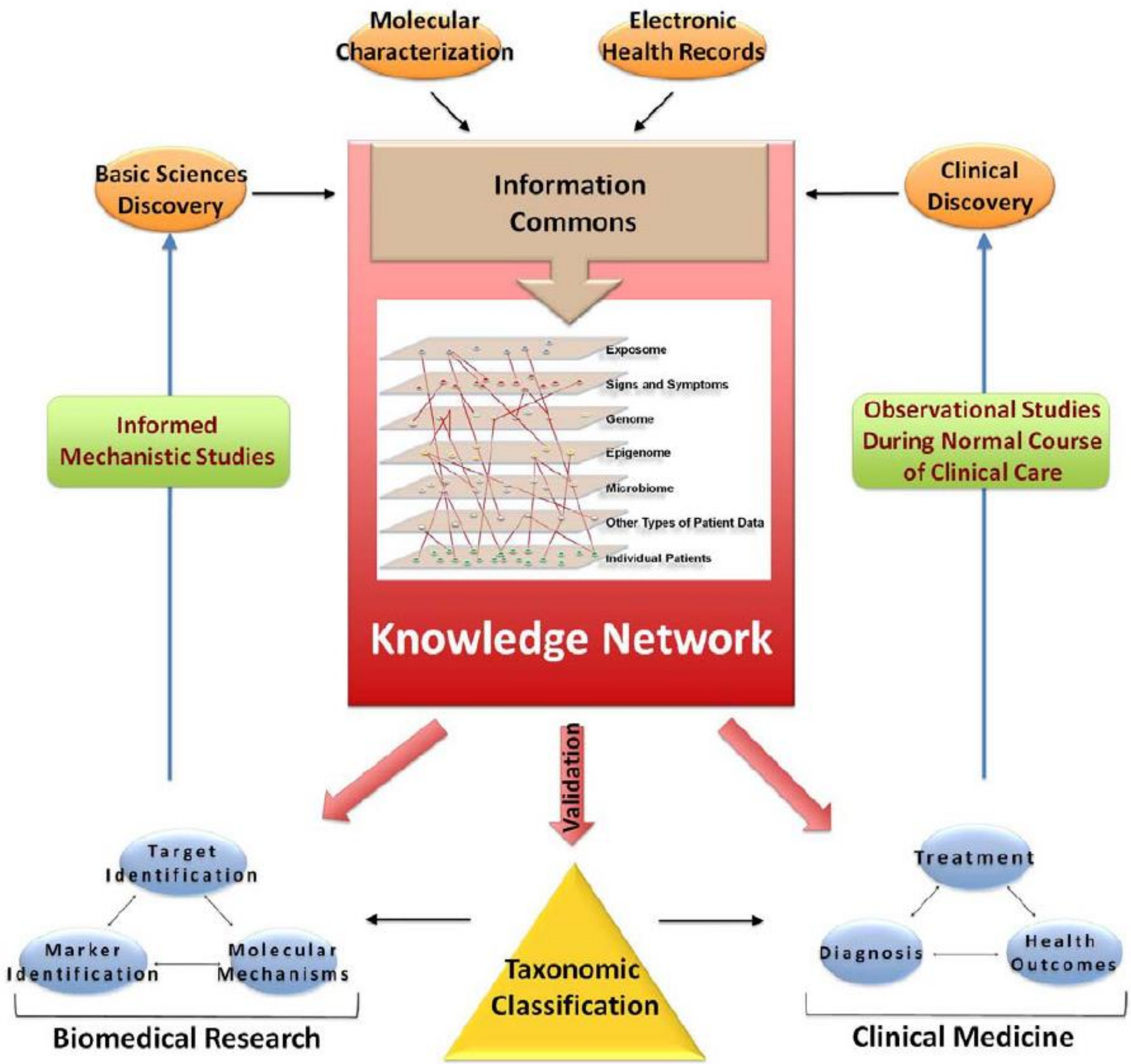


Figure 2-2: Knowledge of non-small-cell lung cancer has evolved substantially in recent decades.

The traditional characterization of lung cancers based on histology has been replaced over the past 20 years by classifications based on driver mutations. In 1987, this classification was rudimentary as only one driver mutation had been identified, KRAS. However, the sophistication of this system for molecular classification has improved with the advent of more genetic information and the identification of many more driver mutations. Similar approaches could improve the diagnosis, classification, and treatment of many other diseases.

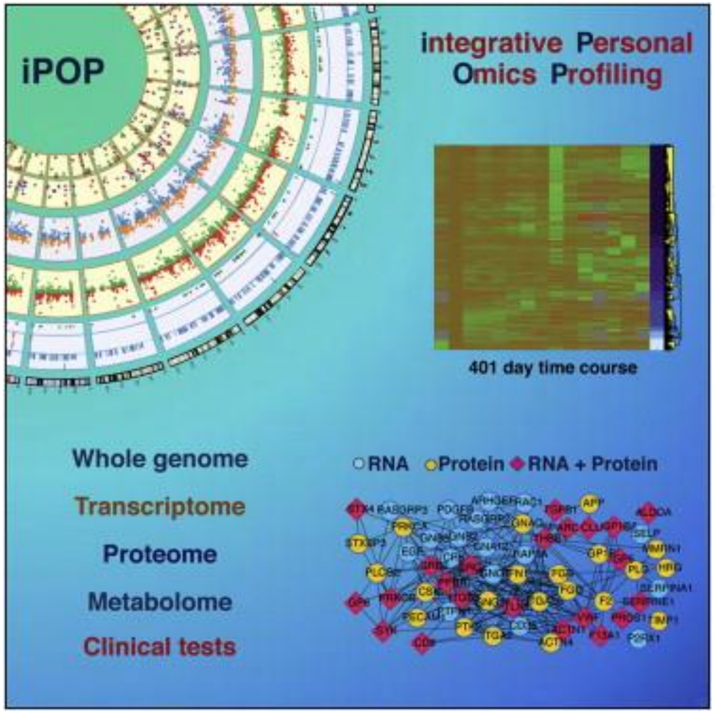
Source: Pao and Girard 2011

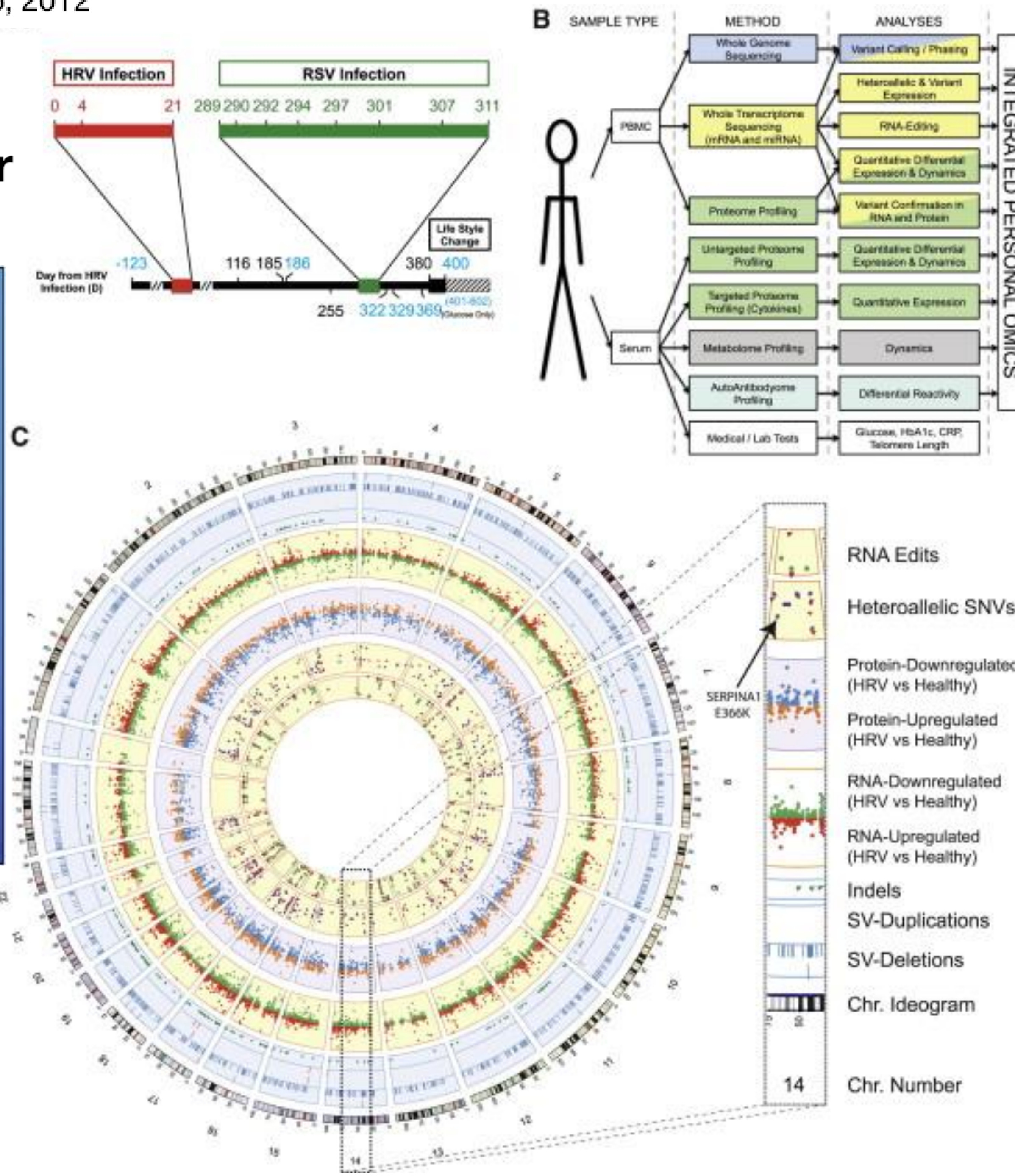
Figure 3-1: Building a Biomedical Knowledge Network for Basic Discovery and Medicine.



Cell *148*, 1293–1307, March 16, 2012

Personal Omics Profiling Reveals Dynamic Molecular and Medical Phenotypes





NATURE BIOTECHNOLOGY | NEWS AND VIEWS

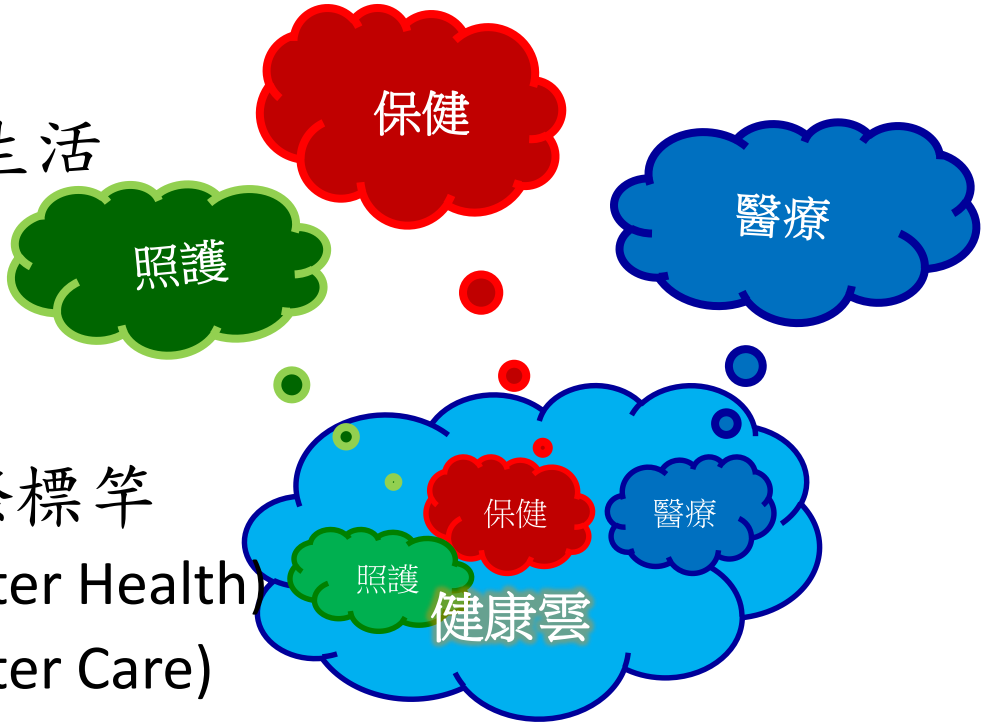
Omics gets personal

Laura DeFrancesco

Nature Biotechnology **30**, 332 (2012)
Published online 10 April 2012

健康雲的內涵

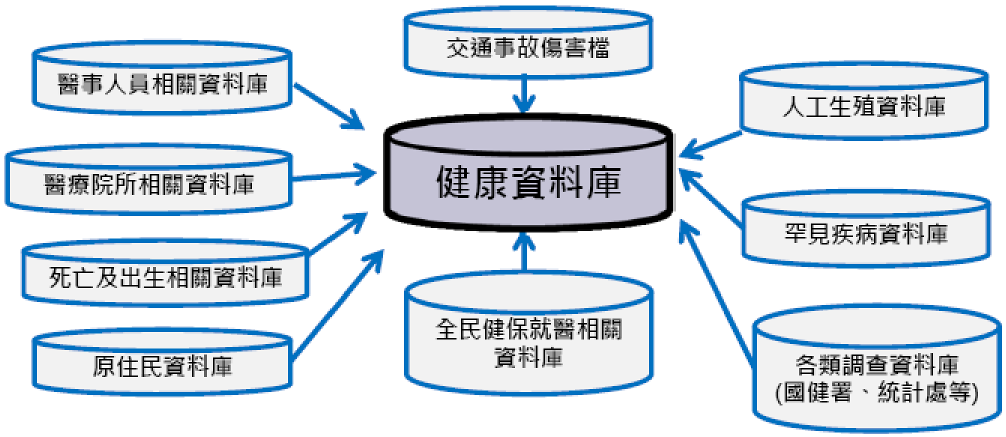
- 塑造全方位的健康優質生活
  - 平時：全時保健
  - 病時：個人化醫療
  - 年長：長期照護
- 塑造 ICT 智慧應用的國際標竿
  - 保健雲 =>優質健康 (Better Health)
  - 照護雲 =>照護提升 (Better Care)
  - 醫療雲 =>短期：資源最有效運用 (Lower Cost)
    長期：個人化醫療 (Personalized Medicine)
  - 健康雲 =>政府福利、產業發展並重的永續經營 (Sustainability)

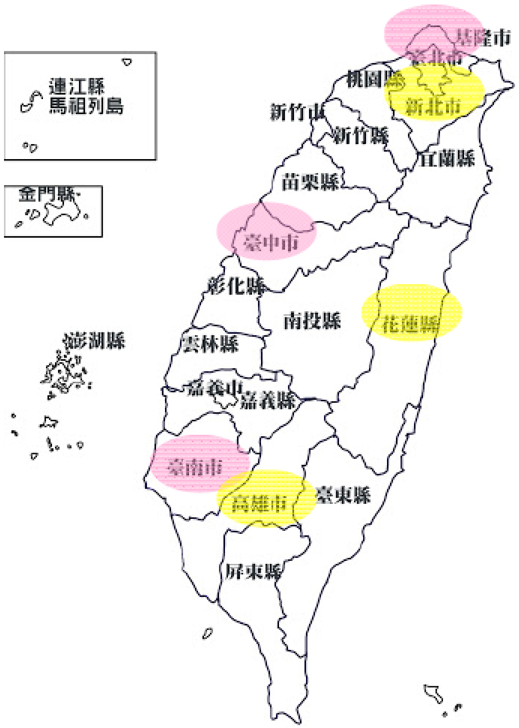


健康資料加值應用雲端化服務-執行現況

Ministry of Health and Welfare

- 健康資料加值應用協作中心分布
  - 已成立：台北車站協作中心、中國醫大、台北醫大、台灣大學、成功大學、 高雄醫大
  - 規劃中：陽明大學、長庚大學、慈濟大學
- 擴充健康資料庫資料檔種類 ※ 每年約25億筆資料





- 研發 R線上統計分析暨導引系統
- 建置指標查詢服務系統

健保資料庫運用： 鳳梨 vs. 鳳梨酥

?

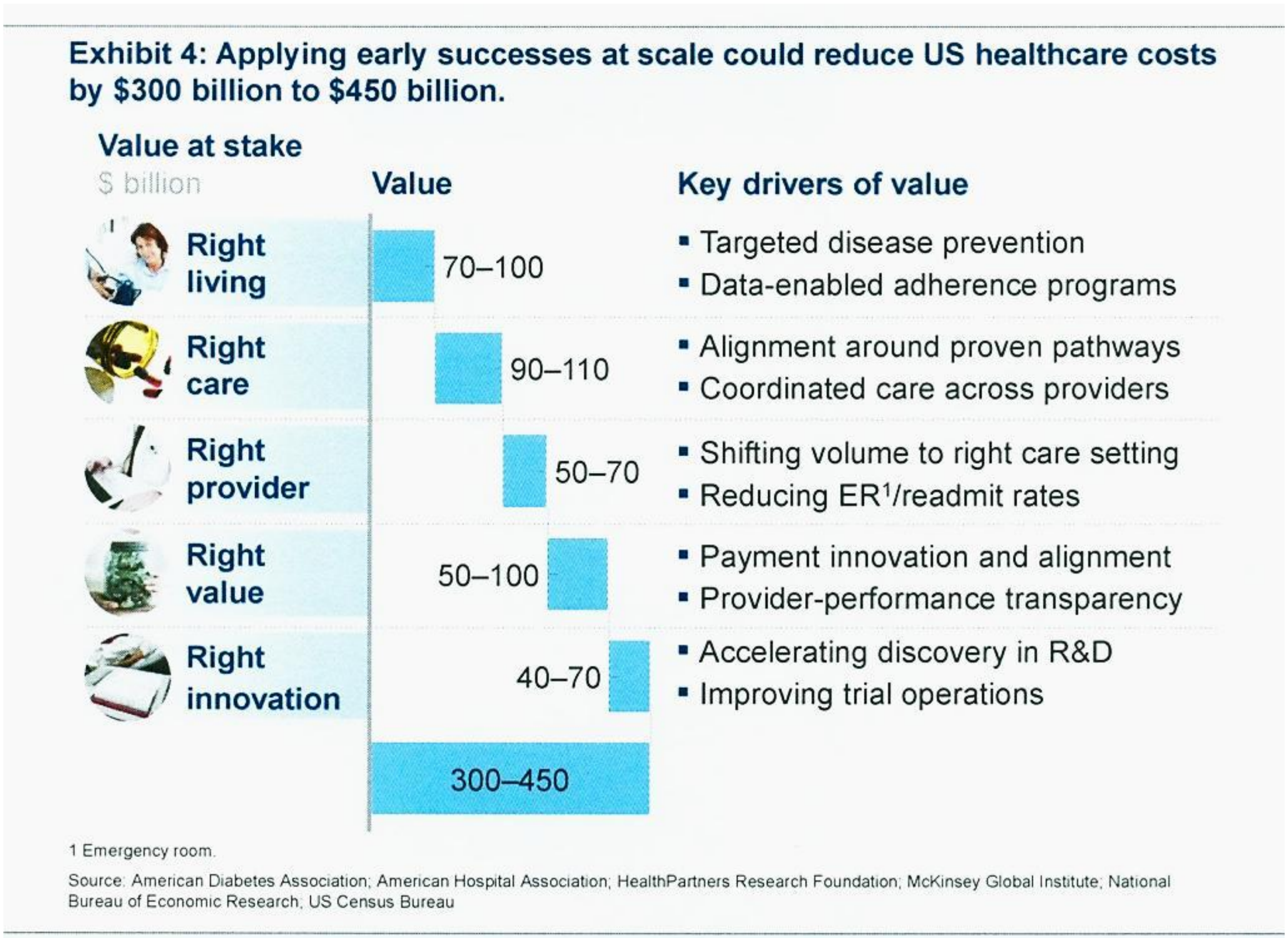
McKinsey,
Jan. 2013

Center for US Health System Reform
Business Technology Office

The 'big data' revolution in healthcare

Accelerating value and innovation

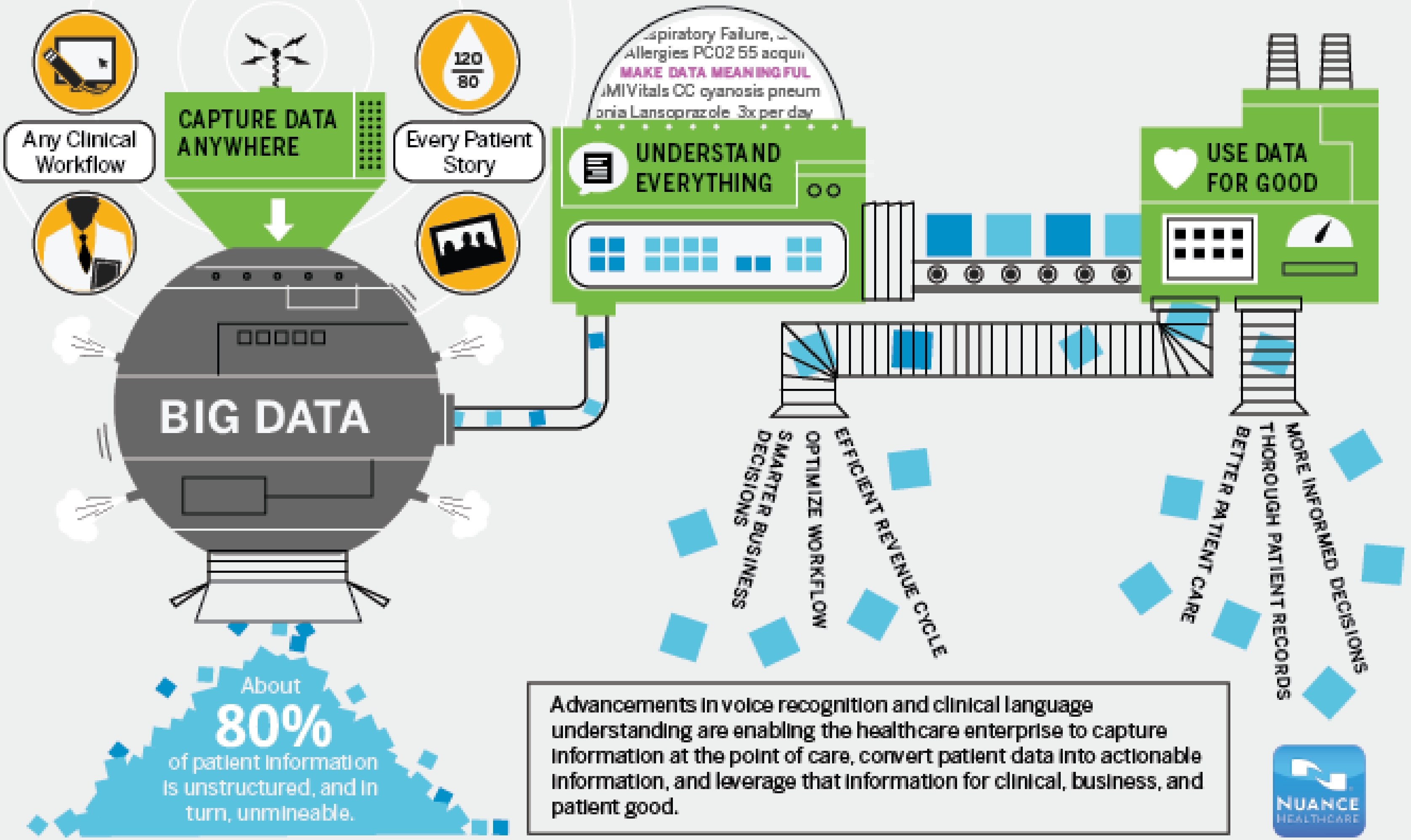
The value of big data in health care = $300-450 billion



HEALTHCARE'S DATA CONUNDRUM

FROM DISPARATE DATA TO MEANINGFUL INFORMATION

We can empower healthcare organizations, providers and payers to unify the capture, analysis, and use of data to drive smarter care and business.



Advancements in voice recognition and clinical language understanding are enabling the healthcare enterprise to capture information at the point of care, convert patient data into actionable information, and leverage that information for clinical, business, and patient good.

www.nuance.com/for-healthcare

6 Keys to the Future of Big Data in Healthcare Marketing

Big data is forecast to make a big difference in the future of healthcare, according to a recent report by the **Ewing Marion Kauffman Foundation**. (April 19, 2012)

1. **Figure Out How to Organize and Use Big Data**
2. **Develop Technology That Taps Into Big Data**
3. **Use Big Data for Better Decision Support**
4. **Turn To Big Data to Ease the Flow of Information**
5. **Use Big Data to Increase the Quality of Care and Decrease Costs**
6. **Develop More Mobile Apps and Social Media That Capitalize on Big Data**

Acknowledgement

BOST
行政院科技會報

科技部 Ministry of Science and Technology

NDF 行政院國家發展基金管理會
National Development Fund, Executive Yuan

SiC

Ministry of Health and Welfare
衛生福利部

FDA

經濟部

DOIT 經濟部技術處
Ministry of Economic Affairs

DCB 財團法人生物技術開發中心
Development Center for Biotechnology