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The Impact of Information Technology on Clinical research

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Topics

The Internet explosion

Clinical Research and Technology

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The Internet explosion

322 Million people use the Internet

2003 estimates are 926 million people

49% are not native English speakers

3 year projections number will rise to 75%

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The Internet explosion

WAP – Wireless Application Protocol
Puts internet in hands of non-computer owners.

Number of mobile subscribers
expected to reach 1.2 billion by 2003

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The Internet explosion

175 million web pages of information on the Internet.

12 month period to July 99 over 33 million US adults used Internet to find health and medical information.

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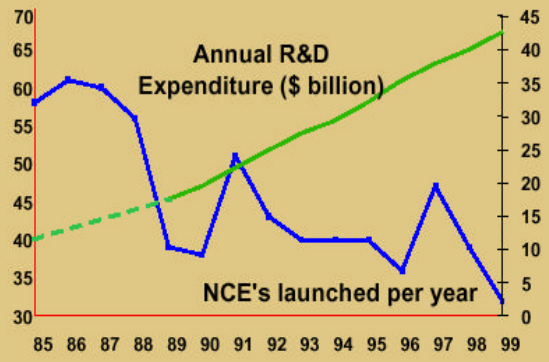
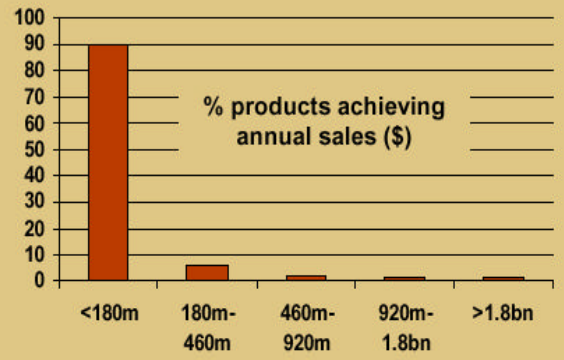
Issues facing Pharmaceutical Industry

John Cline President

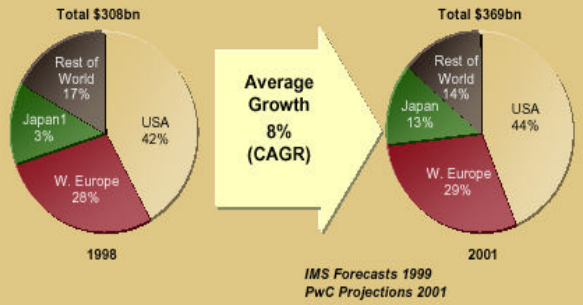
Reducing R&D Productivity



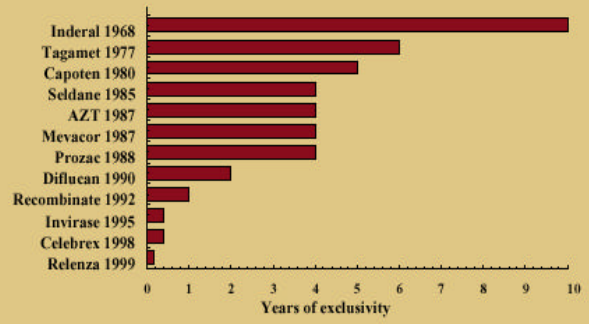
Reliance on Blockbusters



Decline in Market Growth



Increased Therapeutic Competition



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ECPI 2000 Pack

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Rank	Corporation	1999 R&D $ Million	Number of Products in Pipeline: Total #	Phase III	Pre-Reg'd	Potential BB's*
1	Glaxo SmithKline	3,584	269	18	7	2
2	Pfizer	3,595	245	11	6	1
3	Merck	2,068	145	5	2	0
4	Astra Zeneca	2,472	99	3	2	2
5	BMS	1,663	88	8	6	1
6	Novartis	1,705	106	14	2	2
7	Aventis	2,386	191	10	8	1
8	J&J	1,670	79	7	3	1
9	AHP	1,464	155	5	7	1.5
10	Pharmacia	2,495	164	7	6	0

** Expected launches 2000 to 2003*

Source: IMS Health

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- Pharmaceutical drugs remain the 6th largest cause of death in the US
- On average, only 40% of individuals benefit from a particular drug
- Drug development costs have risen to over $600million per drug
- Many medical needs remain unmet
- Regulators struggling with risk versus benefit equation

A new model is needed to produce **safe, efficacious and affordable** drugs

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Current Process

Independent

Departmental and Geographic

Very little cross fertilization of process

From current environment	To future environment
Established and multi-layered	Fluid and flat
Reluctant to change	Change is welcomed
Success judged as control of people or resources	Success judged as delivery of objectives in project environment
Academic conservatism and science focus	Business driven and risk aware
Generally autocratic style of management	Process/project based organisation, multi-point decision criteria
Narrow personal development opportunities	Multi-career paths encouraged and supported
Traditional recruitment paths	Recruitment and recognition of new skill types
Some cross functional groups but rarely international	Cross functional groups from early discovery with international steering/ common interest groups

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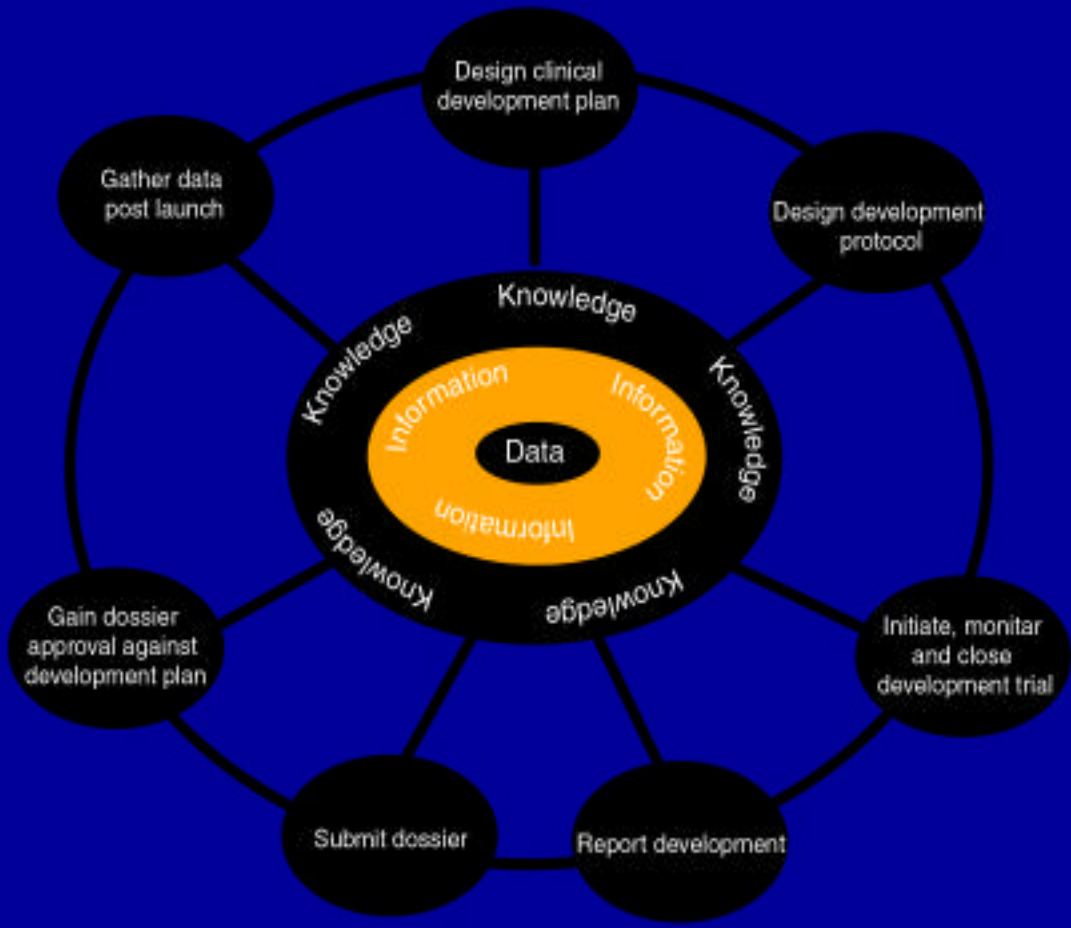
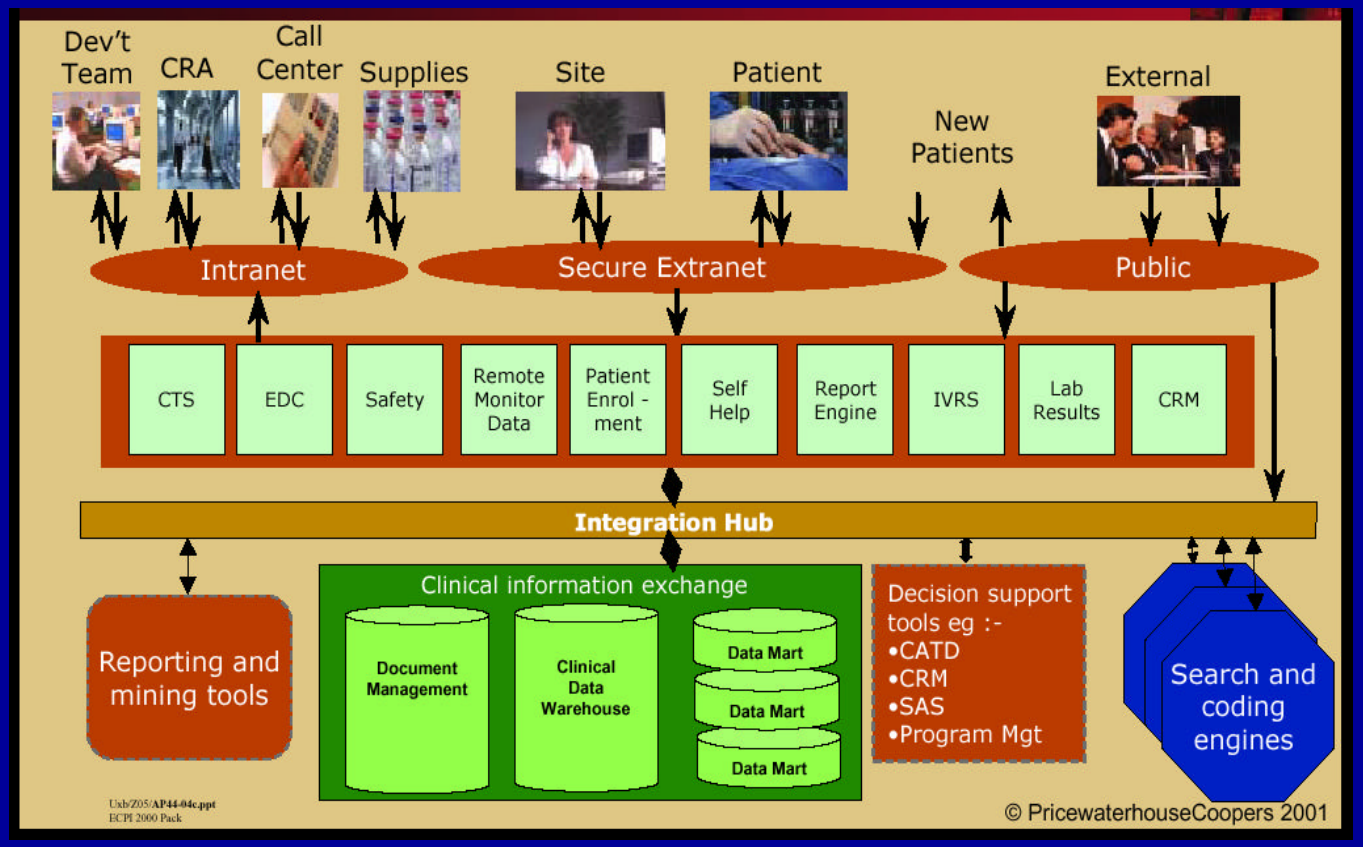


John Cline President


Dev't Team
CRA
Call Center
Supplies
Site
Patient
New Patients
External
Intranet
Secure Extranet
Public
CTS
EDC
Safety
Remote Monitor Data
Patient Enrol - ment
Self Help
Report Engine
IVRS
Lab Results
CRM
Integration Hub
Reporting and mining tools
Clinical information exchange
Document Management
Clinical Data Warehouse
Data Mart
Data Mart
Data Mart
Decision support tools eg :-
•CATD
•CRM
•SAS
•Program Mgt
Search and coding engines
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	Today's challenges	Tomorrow's opportunities
Computer Aided Trial Design & Simulation	•Trial design and simulation •Ongoing trial review	•CDP design and simulation •Ongoing trial review
Integrated Relationship & Trial Management	•Internet recruitment •Trial intranets/extranets •CRM, Call centers	•Connected investigator, patient, supplier and pharma community
Electronic Data Capture & Management	•EDC/IVRS/WAP/PDAs •Integrated reporting	•Electronic medical records •Remote patient monitoring •Data and workflow integration
On-line Analysis, Reporting & Review	•e-Submissions •Rolling review	•Open access ongoing review for Reg Auth's to slice and dice data

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Technology will *initially* create as many problems as it solves

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Technology and Process Change

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Success

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Summary

Paper is inefficient

Internet/technology is not going away

Target molecules will increase

Workforce shortage is real

R&D costs must decrease to meet shareholder expectations

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Call to action

March to the future

Attempt to minimize FUD factor

Properly analyze the “make versus buy” decision

Form strategic partnerships

Set proper expectations

If you are not prepared to change process
DO NOTHING

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THANK YOU

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John Cline President