

FDA: Six priority public health challenges in 2004/ 6



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- ❑ Biomarker development
- ❑ Streamlining CT's
- ❑ Bioinformatics
- ❑ Manufacturing
- ❑ Antibiotics and countermeasures to combat emerging INF and BIOTERRORISM
- ❑ Dev. Therapies for children and adolescents

New science is changing healthcare...



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Structural Biology	Rational design of new medicines
Genetics, genomics and proteomics	Better targeting of medicines
Metabonomics	Better diagnosis and monitoring
Vaccines and immunomodulation	Prevention and monitoring of infectious diseases
Point of care diagnostics	Faster diagnosis and enhanced involvement of the patient
Bionics	Organ replacement and enhancement
Cell and tissue engineering	Regenerative medicine
Imaging	Better diagnosis and precision treatment
Micro-electronic devices	Sensing and monitoring; increased independence for individuals
Minimally invasive and robotic surgery	Enhanced precision and reduction in unwanted drama



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New science is changing health care ... Pharmacology is changing drug development!

Pharmacology is changing drug development



- ❑ Emerging world of **PERSONALISED MEDICINE**
- ❑ Increased use of **BIOMARKERS**
- ❑ Predictive **BIO-SIMULATION**
- ❑ **INNOVATIVE STUDY DESIGNS**
- ❑ **CREATIVE PROCESS DELIVERY**

PERSONALISED MEDICINE



- ❑ Meticulous patient selection
 - ❖ Polymorphisms increase new disease targets
 - ❖ Radical differences
 - ❖ Differences in drug metabolism
- ❑ Greater efficacy, reduced adverse events
- ❑ Variation in response to treatment linked to genes:
 - ❖ Genotype identification kit
 - ❖ Therapeutic kit: diagnostic kit plus medication!

Drug development: The high-Tech Clinical Trial



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- Pharmacogenomics will...
 - ❖ Reduce number of patients in clinical trials
 - ❖ Shorten time-to-market
 - 14.9 years $\wedge \approx 10$ years
 - ❖ Shorten development time
 - 4- 7 years $\wedge \approx 2- 4$ years
 - ❖ Reduce cost of drug development
 - \$1.5 billion $\wedge \approx$ \$200 million

BIOMARKERS



- ❑ Possibility to replace a distant clinical endpoint with more proximal surrogate end point
- ❑ Early elimination of unviable/ unsafe candidates
- ❑ Of great value in optimal/ efficient trial design
- ❑ Technology for biomarker discovery & validation from genomic/ proteomic data are maturing



PREDICTIVE BIO-SIMULATION

- ❑ Use of virtual patients
- ❑ Helps to interpret pre-clinical outputs in the context of human physiology
- ❑ Increased predictability of clinical outcomes
- ❑ Optimal designs of trial protocols
- ❑ Used in identification of appropriate surrogate endpoints and biomarkers



INNOVATIVE STUDY DESIGNS

- ❑ Non-inferiority trials
- ❑ Enrichment designs
- ❑ Adaptive trial designs
- ❑ Analysis of multiple end-points
- ❑ Measuring disease-related symptoms & patient reported outcomes
- ❑ Dose-response relationships in oncology

CREATIVE PROCESS DELIVERY



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- ❑ Electronic data capturers
- ❑ eMedical records (her)
- ❑ Access to patients
 - ❖ Disease epidemiology
 - ❖ Protocol defined patients
 - ❖ Trial-orientated patient populations

Domestic Pharma also needs a robust research infrastructure to sustain



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- ❑ South Africa is an excellent case in point:
- ❑ Strong domestic economy: Strong GDP growth (CAGR 9.4%) with sound fundamentals
- ❑ Growing disease burden: High infectious diseases and non-communicable diseases burden
- ❑ Strong domestic demand:
 - ❖ SA Pharmaceutical industry is growing rapidly
 - ❖ The industry currently estimated around USD 3 Bn +
 - ❖ Expected to touch \$5.4Bn in 2012 at CAGR of 11.8%
- ❑ High quality manufacturing base
- ❑ Business environment for the Pharmaceutical industry may be getting tougher
 - ❖ Administered pricing regulations
 - ❖ Competition from India/China
- ❑ **The domestic industry needs a robust research eco-system to bring new molecules to the market and to address Africa's growing disease burden**



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But there are critical challenges for

the Pharma Industry

AND

The local Regulatory Authorities

Critical challenges.....



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- **Regulations on the conduct of Clinical Trials in Africa**
 - ❖ Vary from country to country
 - ❖ Non-existent in many African countries
- **Intellectual property protection**
 - ❖ Finding the right balance between IP and public health needs
 - ❖ Addressing the concerns of the IP owner
 - ❖ Piracy and counterfeit drugs
- **Regulatory approval delays**
 - ❖ Lack of resources and infrastructure to review protocols
 - ❖ Lack of experienced talent
- **Informed Consent / Possible ethical issues**
 - ❖ Language of consent
 - ❖ Cultural impact on consent process
 - ❖ Impact of illiteracy on consent process
 - ❖ Consent in paediatric studies
- **Investigator experience**
 - ❖ Inexperienced Investigators and Site Staff could have a serious impact on the quality of data collected
- **Infrastructure**
 - ❖ Could be less than optimal at Investigator sites and third party contractors (e.g. local laboratories and couriers)

Loss in FDI / Job opportunities



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- ❑ Global R & D spend \$95 billion
- ❑ Global CRO outsourced \$19 billion
- ❑ Local Pharma industry R2.88 billion
- ❑ Local CRO outsourced R1.73 billion
- ❑ Effect of approval period > 2 months by MCC for clinical trials
 - ❖ Loss of FDI: R286 million per annum
 - ❖ Job opportunities: 326

Regulatory delays cost one S.A. company...



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- ❑ **R109 million in Foreign Direct Investment**
- ❑ **R345 million in Nett New Business**
- ❑ **And 135 jobs**
in 2008 !

Show stoppers – IP related concerns



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- ❑ **Pharmaceutical industry loses billions of dollars globally every year to copies/counterfeits**
- ❑ **IP-related concerns of multinational Pharma – is confidentiality of data submitted for registration/CTA's a given?**
- ❑ **Drug supply and accountability, data submission requirements during development and registration**
- ❑ **Case for improving the domestic research output – Ensuring sufficient protections to make R&D viable**

Show stoppers – Scalability



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- ❑ Global quality, GCP compliant Clinical Research is relatively nascent in Africa, compared to western economies
- ❑ Lack of a large enough pool of experienced clinical development professionals
- ❑ Inability to trigger a reverse brain drain, which many emerging economies are experiencing
- ❑ Dwindling/moderate academic output, resulting in generally anemic talent pools
- ❑ War for talent and resulting high attrition making captive training returns unattractive
- ❑ Dearth of good quality, experienced investigators willing to participate in trials
- ❑ Commercial viability of investigator sites

Case for Public – Private partnership



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- ❑ **Need for proactive Public – Private partnership to build capabilities and infrastructure**
- ❑ **A five point plan towards global competitiveness**

Streamline the regulatory/IP framework

Rationalize the Regulatory/Intellectual property framework to offer faster approval timeframes, less bureaucratic hassles while ensuring subject safety.

Augment the regulatory infrastructure

Industry and Government to work together to bring in talent and augment infrastructure

Work with schools/universities

Industry to work with Schools and Universities to augment/tailor the curriculums to better shape students to meet the needs of the clinical research industry

Vocational bridge programs

Industry or private educational service providers to develop targeted bridging courses to address the skill gaps of the college output

Profitable research practices

Work with investigators to conceptualize and build successful research practices

Africa has the potential to be a clinical research powerhouse, But it requires a coordinated effort to build capabilities, streamline regulatory system and to be competitive globally...

We are not like this in South Africa!



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“More than any time in history mankind faces a crossroads. One path leads to despair and utter hopelessness. The other, to total extinction. Let us pray we have the wisdom to choose correctly”

Woody Allen



We are like this!

“Every morning in Africa, a Gazelle wakes up. It knows it must run faster than the fastest lion or it will be killed. Every morning a Lion wakes up. It knows it must outrun the slowest Gazelle or it will starve to death. It doesn't matter whether you are a Lion or a Gazelle... when the sun comes up, you'd better be running.”



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THANK YOU

