THE CHALLENGES AND OPPORTUNITIES FOR GLOBAL CLINICAL DEVELOPMENT – AN INDUSTRY VIEWPOINT

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Overview

- Shared objective of industry and regulators
  - More rapid access to beneficial new treatments for patients worldwide (including those not from the West)

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Key Focus - Asia

- Most experience of requirements for additional data for local marketing authorizations
- Largest emerging markets
- Tendency for largest drug lags

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Traditional Model

- US/Europe development
- ICH E5 bridging
- Local registration studies
  - Fast to patient in US and Europe
  - Significant drug lag in other regions
  - Inefficiencies in repeating studies locally

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Trend Toward Globalization

- Framework for globally harmonized clinical trials under ICH GCP and other ICH guidelines
- Asian countries have adopted, or adapted, ICH guidelines to differing degrees
- A greater acceptance of foreign clinical data and the introduction of bridging studies have helped to speed the process of drug development and the delivery of products to patients in Asia

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Advantages of Global Development

- Global Development will include patients in global studies, contributing to a single database for analysis
- Global Development model can avoid unnecessary studies
- International co-operative clinical trials could enable simultaneous filings and approvals

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Potential Barriers to Globalization

- Regulatory concerns with:
  - Data quality
  - Differences in medical practice

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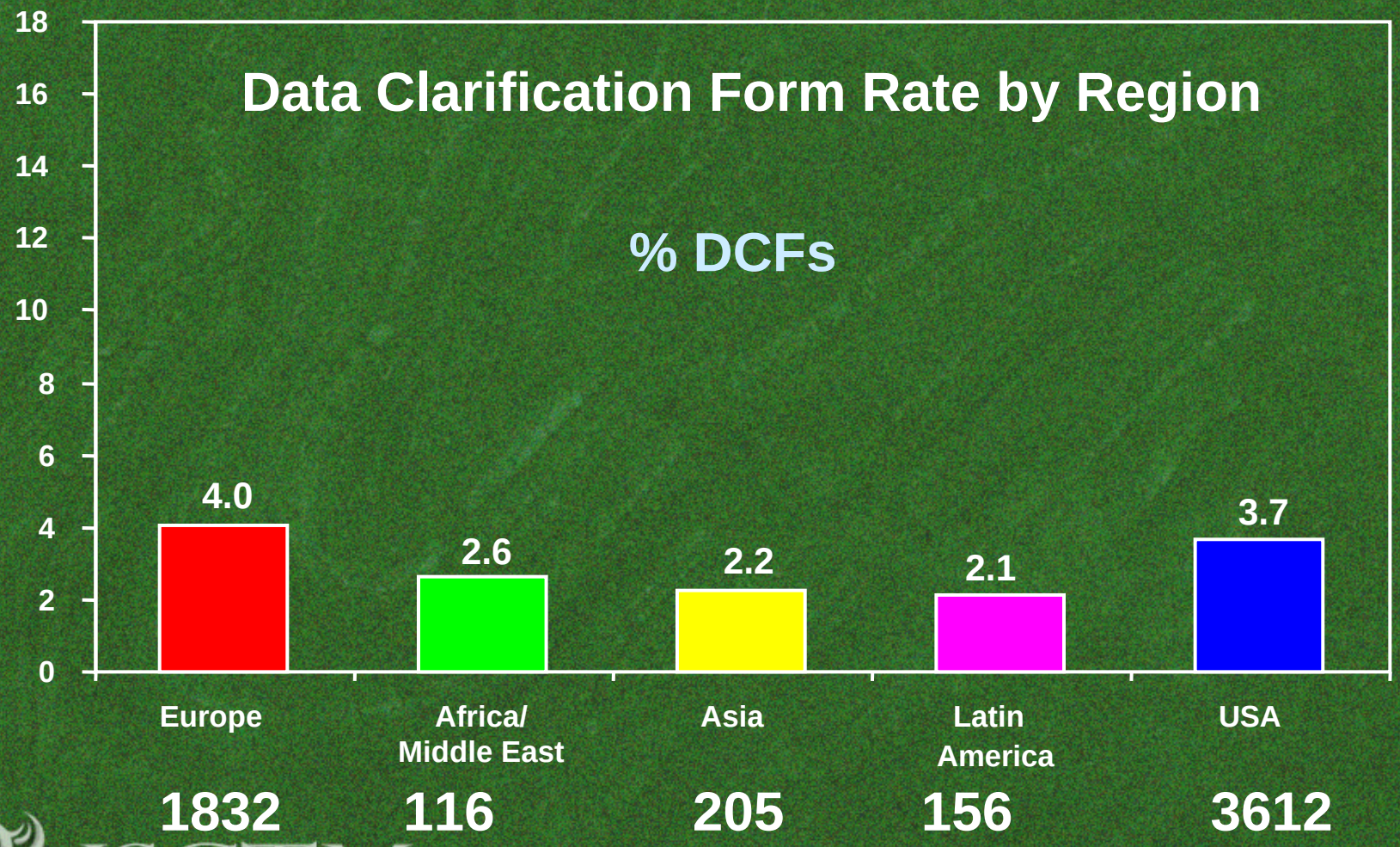
Data Quality Metrics



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Example: Development Challenges in Asia

- Disparate regulatory/clinical environment
  - Need for local clinical data in Japan, S. Korea, China
  - Varied acceptability of Asian data from global studies (vs. local studies)
  - Western data sometimes considered only supportive
  - Relatively long CTA requirements and approval timelines in China
  - Differing approaches to dose selection and labelling philospophies

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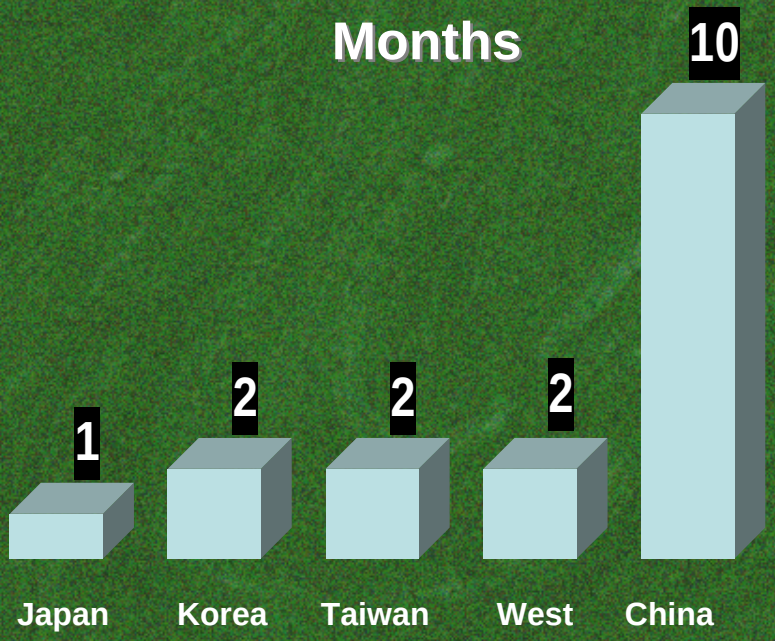
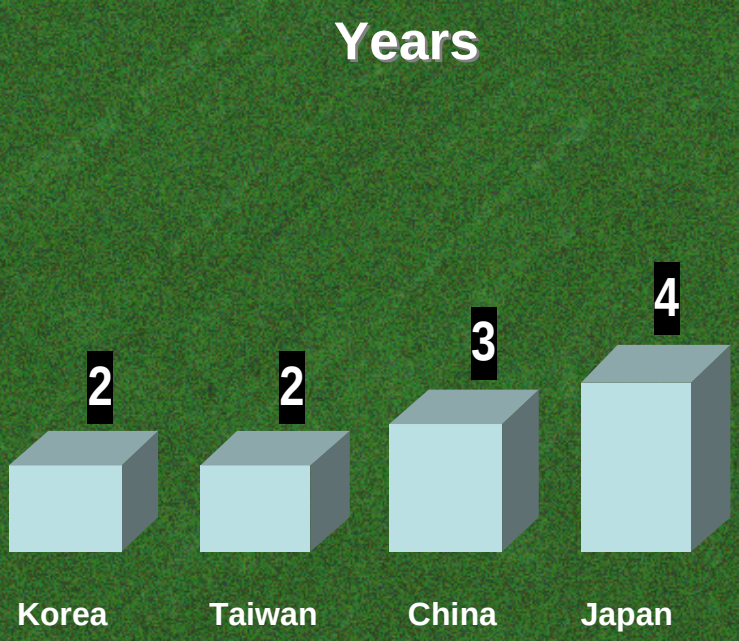
Current Regulatory Challenges in Asia

Approximate Approval Time Variances for INDs/CTAs



Lag in the Introduction of Innovative Pharmaceuticals After Initial Launch



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Achieving Ideal Scenario

Opportunities?

- Increase collaboration between agencies
- Exchange assessment reports
- Global adoption of ICH Guidelines
- Partial recognition of assessment of Asian data
- Shared review of regional data

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The Pfizer Experience (2006)

There are cultural differences related to the target condition, and in therapeutic approach, in Asia compared to the West.

Asian studies:

- No PK differences
- Japanese bridging
- Japanese dose – response
- Asia Regional Study including Korea & Taiwan
- Korean bridging study
- Local Chinese Development in line with Category 1 application

Pfizer anticipates approvals:

Korea: approx 1 yr after West

Taiwan: approx 1.5yrs after West

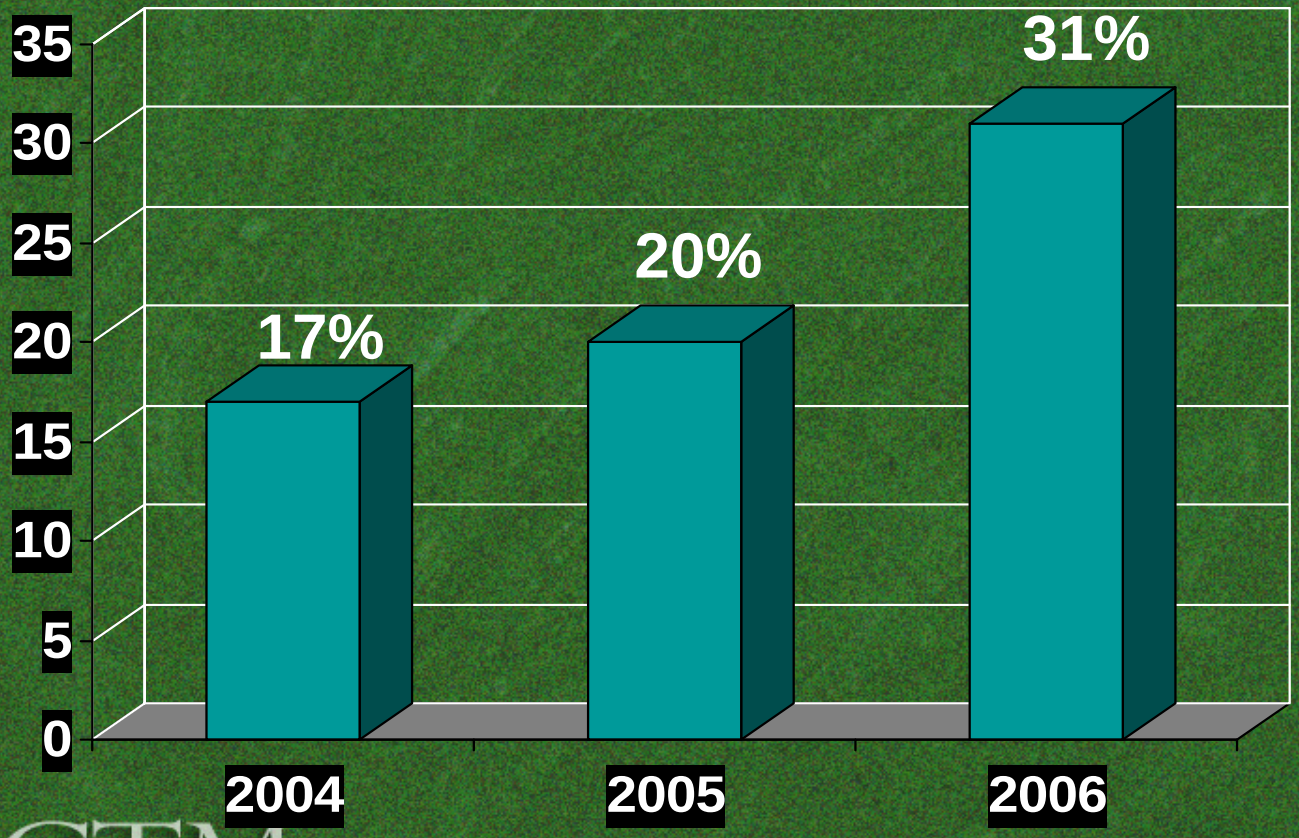
China: approx 2.5yrs after West

Japan: approx 1.5yrs after West

How would approval timelines be affected if a global development model were used?

Increased Engagement

Pfizer WW Medical: % of Clinical Trials with Sites in Asia



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Ideal Scenario

- Common objectives and strong collaboration between Regulatory Agencies and Industry
- A dynamic regulatory environment that has the drive for positive change
- A transition in emphasis from bridging to global development
- Global development leading to simultaneous global regulatory approvals

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Shared Goal

More rapid access to beneficial new treatments for patients everywhere

- Global development is a logical evolution
- Global development could facilitate the delivery of important new treatments
- Changes in the regulatory environment would be needed to take full advantage of the opportunities presented by global development

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