Medical Innovation – Changing Business Models
(A joint technical symposium by WHO, WIPO and WTO)
Geneva, 5 July 2013

BILL & MELINDA
GATES foundation

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Funding Options and IP

Grants:

    Grantees manage project and resulting IP to ensure that "Global Access" is achieved.

Contracts:

    Foundation generally takes ownership in IP that arises under contract (in particular for studies, reports, videos, software, etc.), and takes a license to any incorporated IP.   But complex contracts often require close negotiation of IP rights.

Program Related Investments (PRIs):

    Provisions on IP varies depending on nature of investment (loans, equity, guarantee) and nature of project (supporting R&D v. manufacturing capacity). Can include commitments regarding licensing, manufacturing, quantity or pricing

For All Investment Types, IP Managed to Achieve Global Access

Global Access

Foundation Guiding Principle: Science and technology have great potential to improve lives around the world

Primary Goal of Global Access: to conduct and manage foundation funded projects and the resulting products, services, processes, technologies, materials, software, data or other innovations (collectively, "Funded Developments") in a manner that ensures "Global Access."

Global Access Requires That :

➢ knowledge and information (including data) gained from the projects be promptly and broadly disseminated, and

➢ Funded Developments be made available and accessible at an affordable price (i) to people most in need within developing countries or (ii) in support of the U.S. educational system and public libraries, as applicable to the funded projects.

Measurement and Data – Thoughts from Bill Gate's Annual Letter

- Vision: "You can achieve amazing progress if you set a clear goal and find a measure that will drive progress toward that goal"

- Global Application: The eight Millennium Development Goals in 2000 "was the first time goals that called for specific percentage improvement were picked across a set of crucial areas—such as health, education, and basic income."

- Disease-Specific Example - Polio Eradication: Problems in ensuring coverage of vaccination campaigns can be addressed through use of high-resolution satellite images and use of phones equipped with a Global Positioning System (GPS) application for the vaccinators to carry.

- Conclusion: "The process I have described - setting clear goals, picking the right approach, and then measuring results to get feedback and refine the approach continually - helps us to deliver tools and services to everybody who will benefit."

Our Approach to Giving

We aim to ensure that our investments achieve the highest possible impact, for the greatest number of people, over the longest period of time.

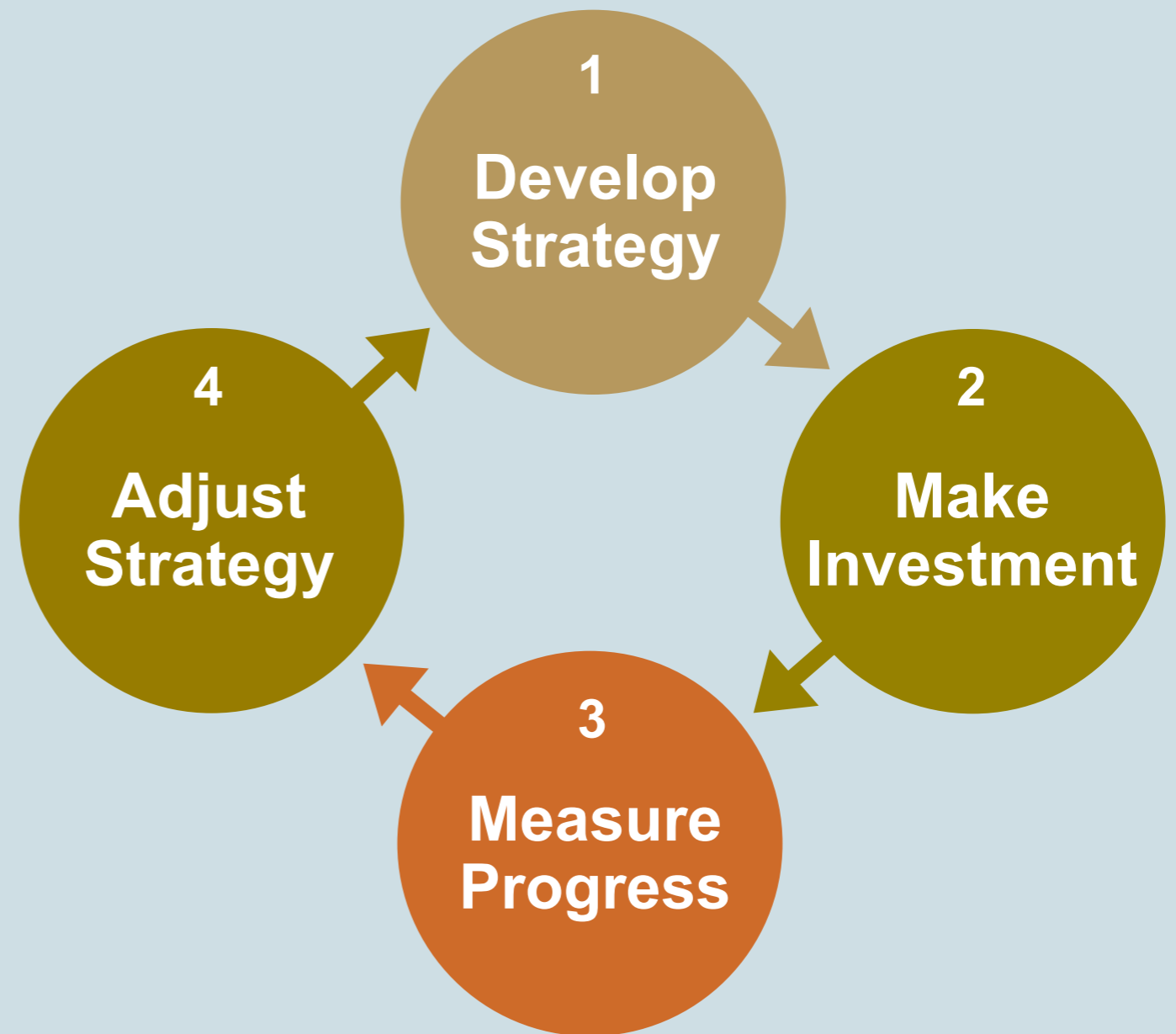**STEP ONE**
Develop Strategy

STEP TWO
Make Investments

STEP THREE
Measure Progress

STEP FOUR
Adjust Strategy

1
Develop Strategy

4
Adjust Strategy

2
Make Investment

3
Measure Progress

Similar Emphasis on Data in Tri-Lateral Report

- "... [T]here is indeed great potential, still mostly untapped, for the use of empirical data to inform policy debate on health innovation and access to medicines. ... [A]ll of us who care deeply about health innovation and access to medicines would benefit from improved accessibility of these raw data, but also from the careful putting together of all the pieces of the empirical puzzle." *Pascal Lamy, Director-General, WTO*

- "Better, more comprehensive and more accessible data on prices, access, patents and trade, enhancing the empirical base for informed priority setting and policy decisions."

- The "quality and availability of empirical data on a range of interconnected factors [has improved], including the global health burden, access and pricing of medicines, regulatory and trade policy settings, and national IP systems."

Data-Driven Elements To Address Burden of Disease

- Identify Global Burden of Disease

- R&D to Address Burden

- Gap Analysis

- Prioritize Diseases & Conditions

Burden of Disease

- WHO Burden of Disease Data:
  Basehttp://www.who.int/topics/global_burden_of_disease/en/

- Global Burden of Disease Study 2010:
  http://www.healthmetricsandevaluation.org/gbd

- This data is essential to understanding current state – before needs for additional interventions can be identified and R&D undertaken.

Data Resources for R&D Funding

- <u>G-Finder:</u> Surveys R&D in 31 neglected diseases and tools to prevent, control and treat them

- https://g-finder.policycures.org/gfinder_report/

New Directions for International Cooperation

- Cooperation to improve existing data resources

- Intellectual Property Information & Licensing

  - Medicines Patent Pool Patent Status Data Base (WIPO) – Landscape Analyses and Assistance on Freedom to Operate

  - WIPO and WHO cooperation to provide IP landscape analyses and licensing advice for prioritized diseases & conditions

- Limitations on cooperation: Many IP issues are transaction specific and not susceptible to global treatment

Example: Data on Regulatory Approvals

- Regulatory Approvals at National Level:

  "Convergence of the different national systems, in conjunction with harmonization of technical requirements, can remove many of the transactional and human resource costs associated with multiple regulatory submissions in each country, including multiple testings."

- Processing of Patent Applications at Regional and National Levels:

  Convergence of standards and common form and content, improved access to data pertaining to prior art can similarly remove costs associated with multiple submissions in all countries.

- WIPO and WHO can:

  - share experiences in examining multiple dossiers (drug regulatory approval and patent applications) applying common legal standards to common facts

  - Cooperate on addressing data exclusivity norms – to be clear, this is not a suggestion of any "linkage" between patents and regulatory approvals, but a suggestion that there may be common process and systems solutions for the two subjects

Concluding Remarks

- Today, much better data is available globally on areas such as pricing, scope of access to medicines and patent coverage. *f*

    - All of WHO, WTO and WIPO have contributed to this.

- There are a range of areas in which WIPO, WHO and WTO currently cooperate to provide infrastructure to promote R&D toward priorities in global health

- As focus on priorities improves, more opportunities for the three organizations to focus on more specific and practical assistance

Thank You