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BUILDING A HEALTHY FUTURE FOR ALL

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What Motivates Us?

- 36.7 million people worldwide live with HIV
- 53% receive antiretroviral treatments
- 4 million people die annually from HIV, tuberculosis, malaria, viral hepatitis, and other neglected tropical diseases

Social & economic barriers to life-saving medicines → Millions of avoidable deaths

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Improve Access to Affordable & High Quality Medicines

Democratize Pharmaceutical Manufacturing by open sourcing low cost processes to drive price reductions in the marketplace

Reinvent Medicine Supply Chain via vertical integration of advanced starting materials prepared from commodity chemicals & leveraging of flexible manufacturing methodologies that enable direct-to-consumer

Create the Next Generation of Global Scientists by instilling principles and foundations that drive accessibility & self-sustainability

The State of Pharmaceuticals Manufacturing

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Primary Cost Drivers in Today's Active Pharmaceutical Ingredient (API) Manufacturing

Raw Materials

Solvent Consumption

Inflexible Processing Technologies

Lack of Access to Affordable Critical Medicines

Fragile Supply Chain

API Costs

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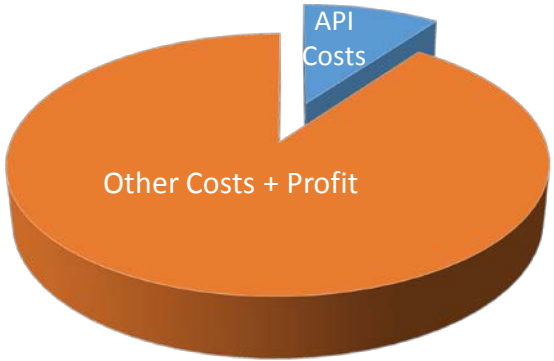
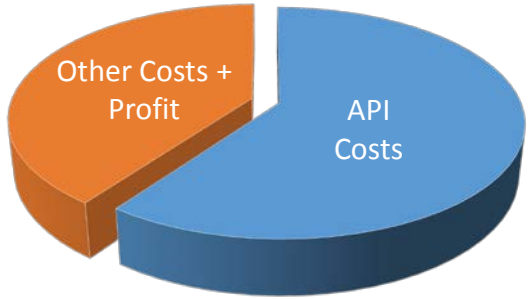
Patented Drug Cost Components



- Limited window for optimization
- Time to market is key driver

Generic Drug Cost Components



API costs drive **40-70%** of the selling price for generic drugs

- Must establish equivalency
- World Health Organization drugs similar to generics landscape

Consequences for Global Health Generics:

- Constrained manufacturer margins (supply chain risk)
- New, low-volume treatments kept off market
- Reduced access to critical meds

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The Opportunity

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Replace inefficient processes with streamlined production of critical medicines

- Reduce API costs so it is a minimal driver of medication price (esp. for generics)
- Develop a process optimization model that is translatable to:
  - -High volume and low volume medications
  - -Drugs in market and in development
- Develop novel manufacturing platforms to facilitate manufacturer AND market uptake
- Generate less waste with "greener" processes

Delivering Chemistry Innovation and Enabling Manufacturing Innovation

To Improve Access to, and Enhance Security of Supply of, Existing and Emerging Global Health Treatments

M4ALL Process Optimization & Implementation Approach

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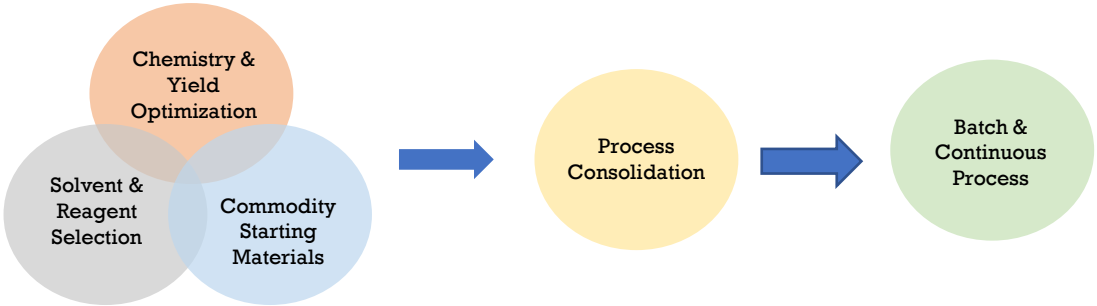
M4ALL Process Optimization
(for priority drug targets)



Address primary cost drivers in existing API manufacturing processes

Manufacturing & Market Implementation

USAID FROM THE AMERICAN PEOPLE

CLINTON HEALTH ACCESS INITIATIVE

medicines patent pool

MMV Medicines for Malaria Venture

Tech transfer partners enable manufacturer uptake of M4ALL processes & tracking of pricing reduction in market

M4ALL Outcomes: Nevirapine

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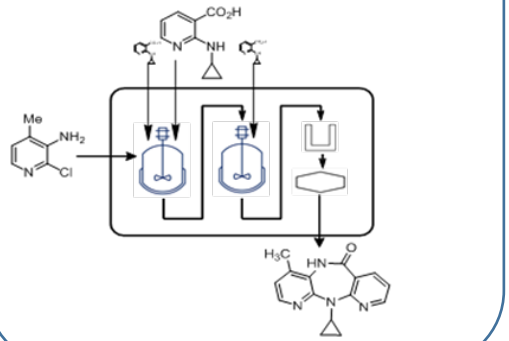
M4ALL Nevirapine Process



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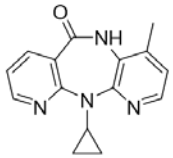
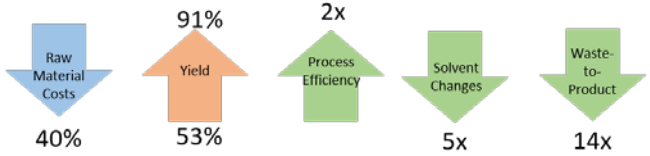
Generic Manufacturers



M4ALL Improvements to Nevirapine Production



Total Price Decrease: **9%**

2015 Savings: **$7.8M**

M4ALL's Portfolio of Targets

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HIV

- Nevirapine
- Tenofovir
- Dolutegravir
- Emtricitabine *(in progress)*
- Darunavir
- Lamivudine (3TC) *(Planned)*

Anti-Malarials

- Artemisinin
- Hydroxychloroquine
- Future plans to pursue new targets

Antibiotics/ Antimicrobials

- Ciprofloxacin
- Fluconazole

Future plans to pursue

- *Tuberculosis drugs*
- *Oncology drugs*
- *Opioid antagonists*

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Open Sourced Processes + Distributed Manufacturing

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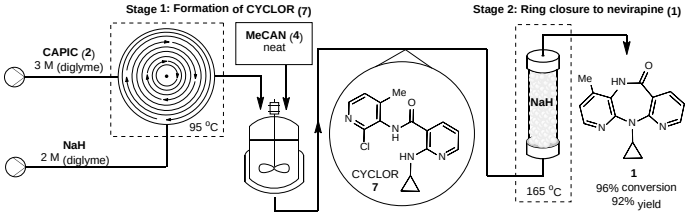
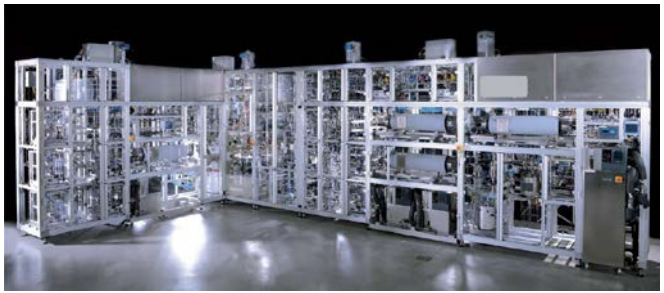
- Suite of COTS & bespoke platforms enables scalability at any level

M4ALL Continuous Process for Nevirapine

Vergese et al, Green Chemistry, 2017, DOI: 10.1039/C7GC00937B





Allford, G.; Hagger, B. *7th Symposium on Continuous Flow Reactor Technology for Industrial Applications*, Delft, Netherlands, Sept 29-Oct 1, **2015**
Roberts, K. *Chemistry and Industry Magazine* **2016**(*6*), p. 31-33

Pharmacy on Demand

Distribute Medicines Anywhere

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- Reduces need for stockpiling
- Smaller footprint provides distribution flexibility
- Empowers regional & in-country (i.e. independence)

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Anticipated Regulatory Science Challenges

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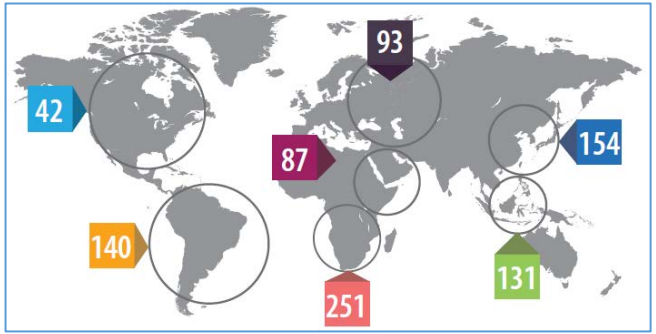
- More players entering the market for global health drugs, including those that are developing continuous capabilities
- Altered, contaminated, and counterfeit products an ongoing global issue
- No reliable, simplified QA/QC for process or products

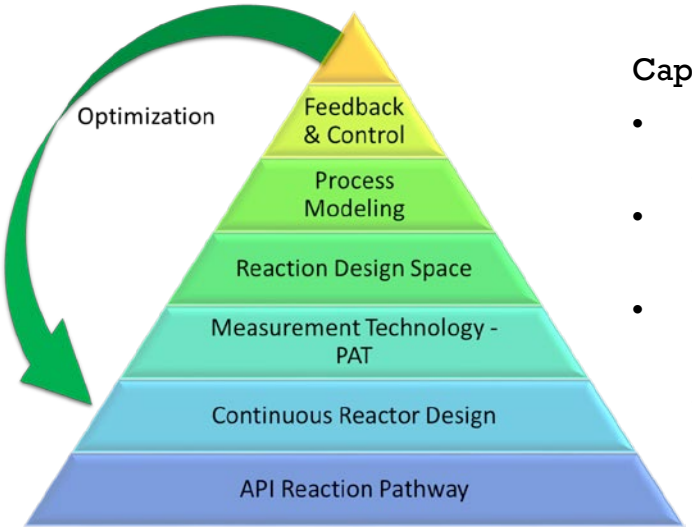
2015 Pharma Partnerships in Global Health

2017 Pharma Partnerships in Global Health



Source: IFPMA

Potential Solutions for Product & Process



Capability to analyze & control quality of reactants & products online:

- Innovative reactor platform capable of developing new chemistry pathways for fast process optimization and control
- Relies on effective measurement technologies, to determine critical process attributes to quickly optimize reaction parameters
- Integrated control of all reactor parameters in a smart systems approach allows for fast screening of reaction space with real-time measurement to provide an agnostic platform for chemical development, optimization, and production

On-line measurement technologies provide feed stock quality & reactor control resulting in quality API products

Potential Solutions for Supply Chain

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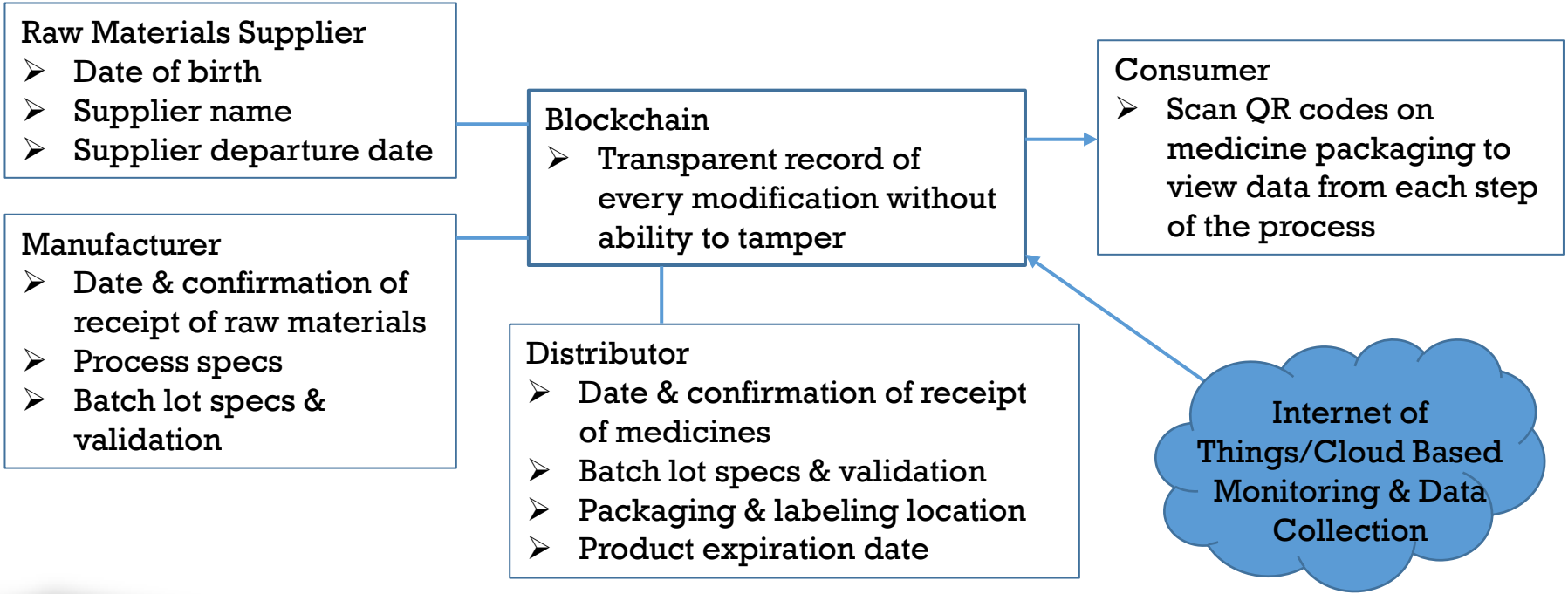
Safe & Secure Tracking of Medicines via Blockchain



Acknowledgements


routes
provide
intermediate
development
capabilities
strategies
optimization
chemistry
provides
marketplace
supply
global
current
work
savings
technology
approach
manufacturing
alternative
analysis
starting
impact
goods
viable
materials
novel
manufacturers
access
partners
medications
unique
Step
target
cost
process
chain
health
integrated
Virginia
reduced
processing
School
effective
develop
Medicines
primary
developing
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margins
Health
Access
ensures
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