# PEQUENAS GRANDES COISAS

## Bringing Vaccine Vial Monitors to Brazil

*Andrew Stearns | Emma Spickard | Sarah Rinehart | Kim Perdue*

# PEQUENAS GRANDES COISAS

Temptime®
Improving Global Health

PATH

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MINISTÉRIO
DA SAÚDE

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MINISTÉRIO DA SAÚDE

Safer & More Effective

# 2019 – 2023 VVMs IN BRAZIL

**2,508**

**LIVES SAVED**

# 2019 – 2023 VVMs IN BRAZIL

**2,508**
LIVES SAVED

×

**$8,649**
GDP PER CAPITA



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**2,508**
LIVES SAVED

×

**$8,649**
GDP PER CAPITA

=

**$21.7 MILL**
ECONOMIC PRODUCTIVITY CREATED

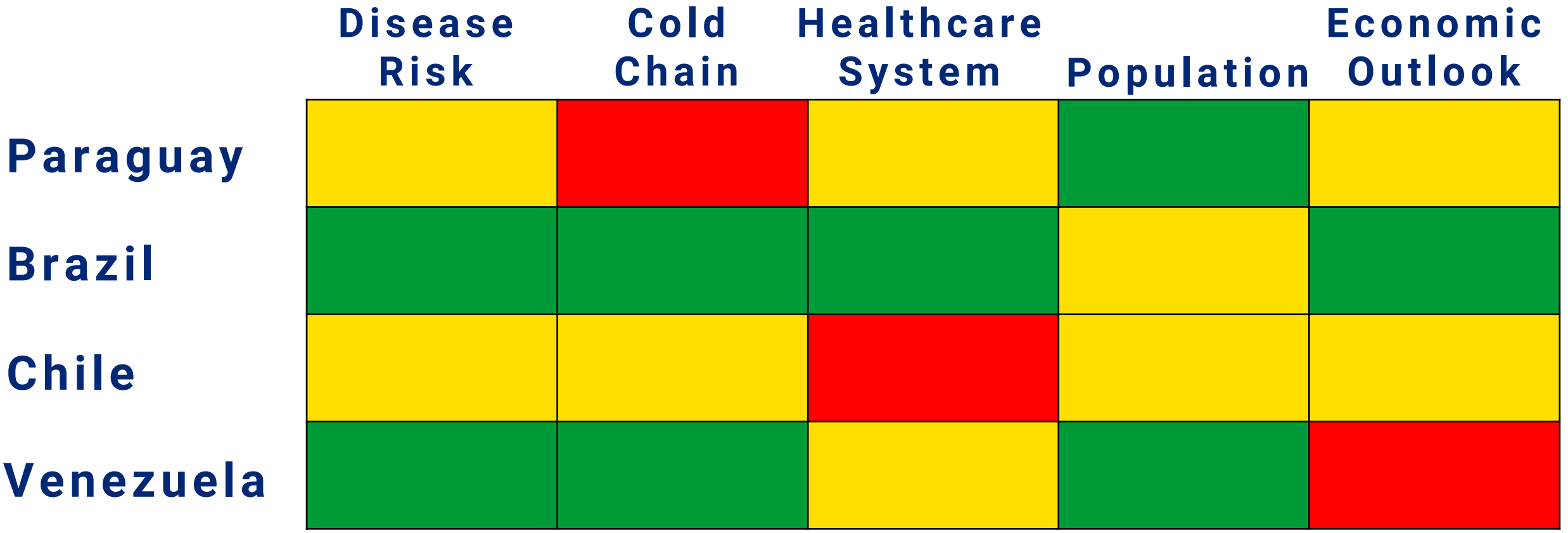
# AGENDA

- Situational Analysis
- Social & Economic Benefits
- Risks & Mitigation
- Timeline
- Financing Plan
- Questions

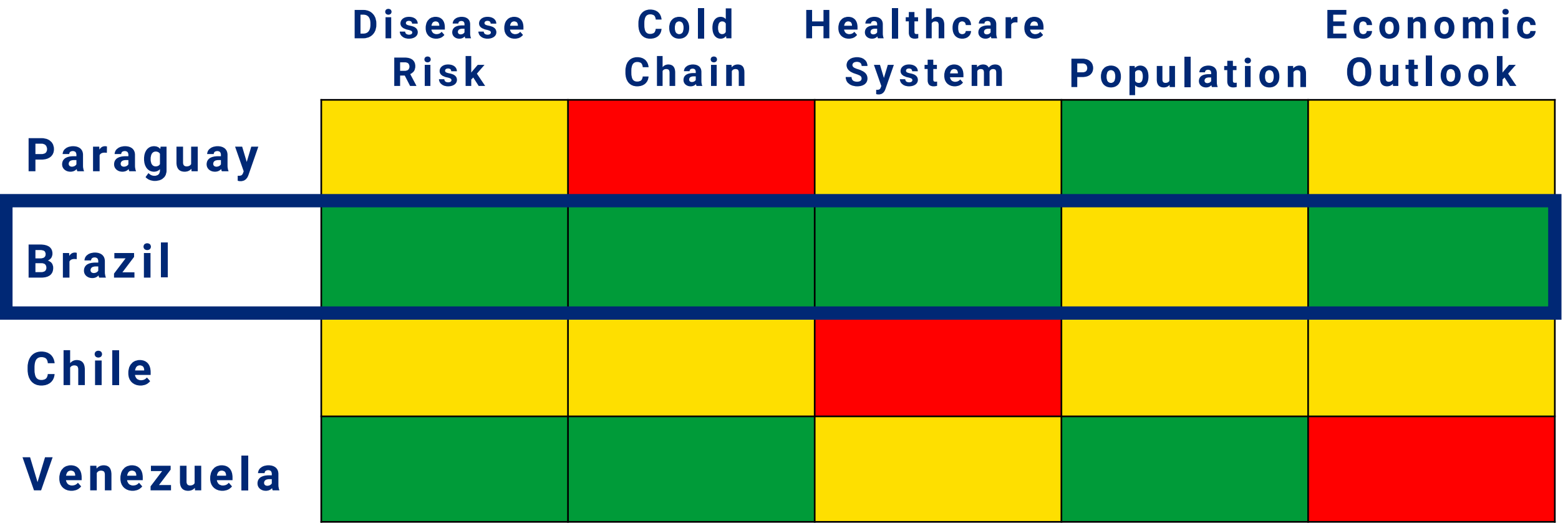
# SITUATIONAL ANALYSIS

## Determining Initial Country of Entry

# COUNTRY ANALYSIS



# COUNTRY ANALYSIS




Analysis Benefits Risks Timeline Financials Summary

# SAO PAULO

## RURAL & URBAN AREAS

## HIGH RISK COMMUNICABLE DISEASE

## RESPONSIBLE FOR 33.9% GDP

# BENEFITS

Immediate & Long-term Benefits of VVM

# SOCIAL BENEFITS

# SOCIAL BENEFITS


# SOCIAL BENEFITS

**2,508**
**LIVES SAVED**

**BETTER TOOL**

**$34,000**
**SAVED PER HEP B PATIENT**

# STAKEHOLDERS

## PUBLIC

PATH

United Nations

PRO SALUTE NOVI MUNDI

FIOCRUZ

MINISTÉRIO DA SAÚDE

# STAKEHOLDERS

## PUBLIC

PATH

United Nations

PRO SALUTE NOVI MUNDI

FIOCRUZ

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## SOCIAL

# STAKEHOLDERS

## PUBLIC

PATH

United Nations

PRO SALUTE NOVI MUNDI

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## SOCIAL

## PRIVATE

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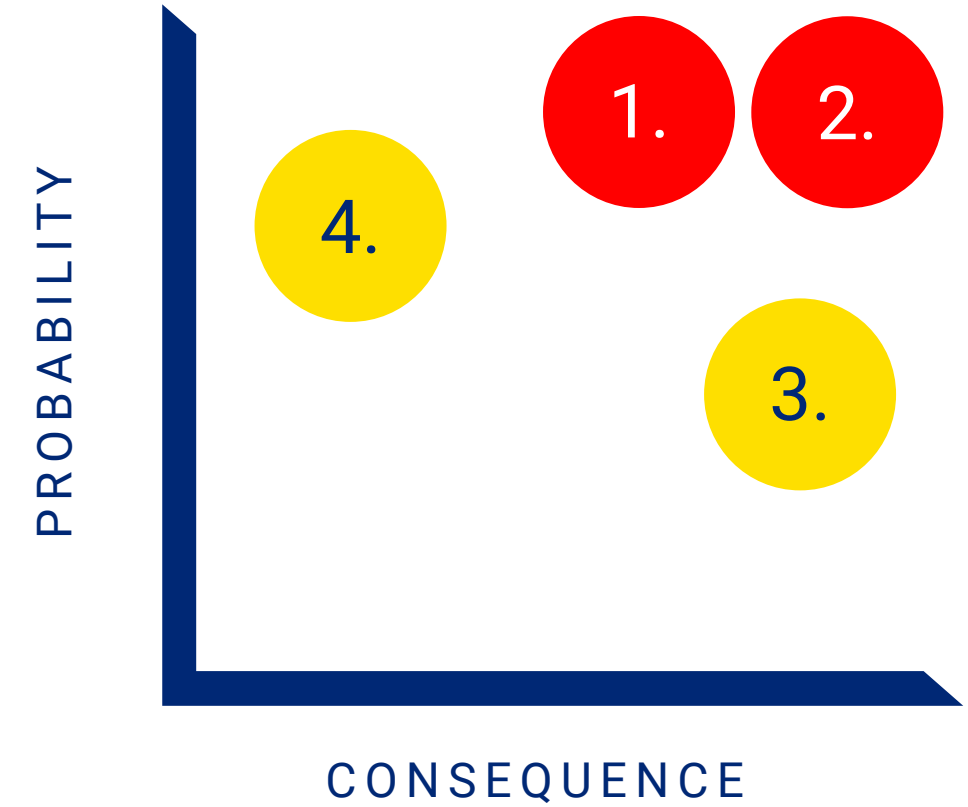
Improving Global Health

# RISKS

Identifying And Mitigating Potential Obstacles

# RISKS & MITIGATIONS

1. COLD CHAIN
2. LACK OF TRAINING
3. TEMPTIME SINGLE SUPPLIER
4. GOVERNMENT PUSHBACK



# COLD CHAIN

No Temperature Monitoring

Difficult Distribution

## INVESTIGATE COLD CHAIN

# TRAINING

Difficulty Reading Thermometer

Poor Supervision

## Como Ler Um VMM

Se a vacina nao estiver for a do prazo de validade, use a vacina

Nao use a vacina Informe seu/sua chefe

Analysis Benefits Risks Timeline Financials Summary

# TEMPTIME SINGLE SUPPLIER

No Other Supplier

## ECONOMIES OF SCALE

# GOVERNMENT PUSHBACK

Don’t Currently Have Regulations

UNICEF RESOLUTION

CHANGING POLITICAL ENVIRONMENT



# IMPLEMENTATION

Timeline of Fulfillment and Future VVM Expansion

# IMPLEMENTATION TIMELINE

## 2018

Exhaust Current Vaccines

PAHO Provides VVM Funds

$2.17 MILL

## 2019

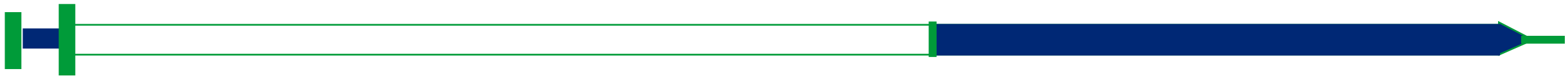
VVM Distribution

Training

Cold Chain Investigation

$0.05 MILL





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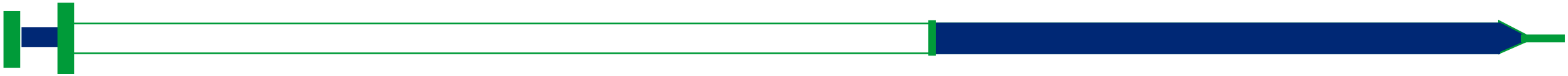

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$0.05 MILL

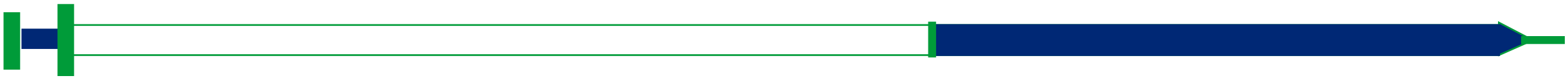
## 2020

UNICEF Resolution

Fix Issues

$0.15 MILL





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## 2021

VVM All of Brazil

$6.17 MILL



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## 2022

Bi-Annual Checkups

$0.05 MILL



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VVM Distribution

Training

Cold Chain Investigation

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## 2020

UNICEF Resolution

Fix Issues

$0.15 MILL

## 2021

VVM All of Brazil

$6.17 MILL

## 2022

Bi-Annual Checkups

$0.05 MILL

## 2023+

Expansion into remaining South American

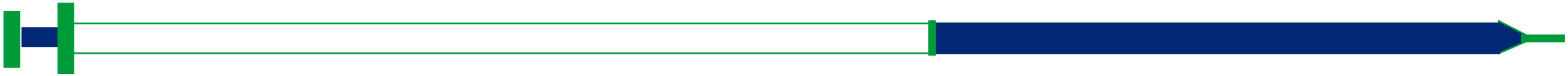
## 2030

Barcodes

Controlled Temperature Chain

UN's Sustainable Development Goals

Analysis Benefits Risks Timeline Financials Summary



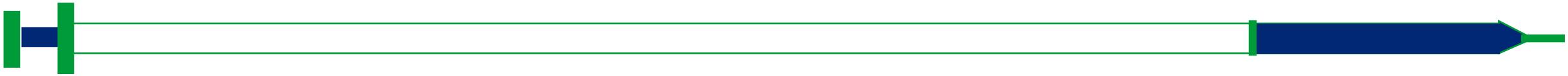
# VISION 2023

**$9.93 MILL**
TOTAL COST

**$21.7 MILL**
ECONOMIC PRODUCTIVITY CREATED

**$11.77 MILL**
NET ECONOMIC PRODUCTIVITY

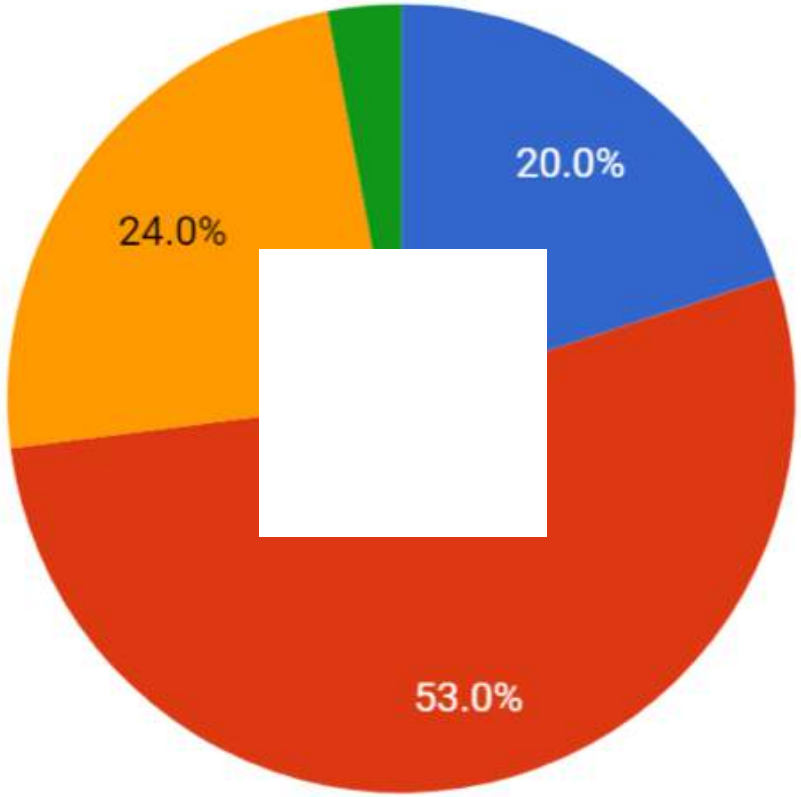




# FINANCING

Analysis of Who Will Financially Support VVM Integration

# FINANCING




Brazilian Government (via PAHO) 53%

PATH / USAID 24%

IPSAS 20%

Temptime 4%

# PEQUENAS GRANDES COISAS

**2,508**
LIVES SAVED

**$11.77 MILL**
NET ECONOMIC PRODUCTIVITY

# APPENDIX

39. Financing Information
40. Financing Sources
41. Brazilian Vaccination Schedule
**42.PAHO IPSAS**
43.Vaccination Supply Chain
**44.GDP vs. GNI**
45.VVM Implementation
46.Coverage Costs Variation
47.Label Machine
48. Unit Costs
**49. Country Matrix**
50. Brazil Disease Burden
51. Vaccine Stability
52. HEP B
**53. EPI**
**54. Lives Saved**

# Financing Information

2018: $672 thousand for VVMs statewide, $1.5 million for VVM labeler = $2.17mill

2019: $25 thousand for Cold Chain investigation, $25 thousand for training nurses $50k

2020: $50-300 thousand for repairing and maintaining Cold Chain $150k

2021: $3.17 million for VVMs nationwide, $3 million for VVM labelers $6.17mill

2022: $50 thousand for first biannual check on Cold Chain $50k

2023: Costs to be determined based on South American countries' economies

# Financing Sources

PAHO IPSAS Surplus Fund. We are aware of the **$4 million** in reserves for strategic initiatives, and we believe some could go toward this cause.

PAHO Revolving Fund for Strategic Health Supplies will help to decrease price of machine due to increased purchasing power.

PATH's mission is to "improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors." They already work in Brazil to improve health systems, and this would give PATH a clearer direction to follow.

# Brazilian Vaccination Schedule

**Table 1.** Brazilian official calendar for vaccinations in 2001[17]

| Age | Vaccine |
|---|---|
| Neonates | tuberculosis and type B hepatitis |
| 1 to 2 months | diphtheria, tetanus and pertussis (DPT), polio*, hepatitis B and *Haemophilus influenzae* type B (Hib) |
| 4 months | DPT, polio and Hib |
| 6 months | DPT, Hib and polio |
| 9 months | measles, yellow fever†, hepatitis B |
| 15 months | measles, mumps and rubella and DPT |
| 5 or 6 years | DPT and polio |
| 15 years | diphtheria and tetanus |

**oral Sabin vaccine is used for polio; †restricted to endemic regions.*

# PAHO IPSAS Surplus Fund

PAHO Financial Statements:

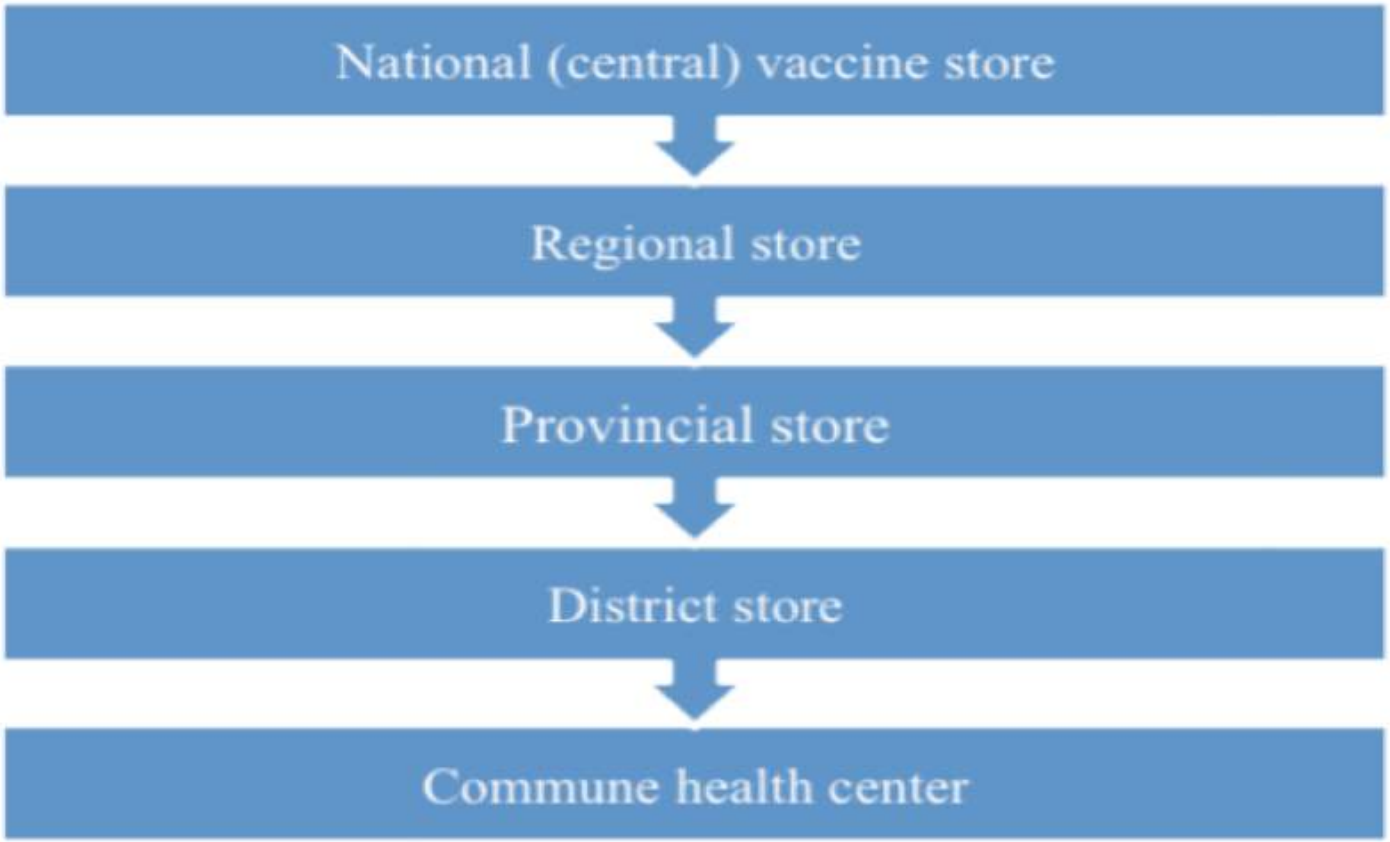
14.12 IPSAS Surplus Fund

The IPSAS Surplus Fund was established by Resolution CSP28.R16 of the 28th Pan American Sanitary Conference, 64th Session of the Regional Committee. This fund will be used to meet future unforeseen strategic and/or administrative initiatives. Future proposals for the use of this reserve may also include increases in any other existing funds.

(g) Reserve—$4,381,684: Although there are many opportunities for investment, it is considered prudent management of resources to leave a modest amount of unallocated surplus funds in reserve to meet future unforeseen strategic and/or administrative initiatives Future proposals for the use of this reserve may also include increases to any of the items listed above, if necessary.

# Vaccination Supply Chain

**Figure 1. Example of a five-tier supply chain**



# GNI v. GDP v. GDP (PPP)

GDP: Baseline economic production of a country each year. Best way to analyze the economic in this case because every dollar value is on the same level.

GDP (PPP): GDP adjusted to reflect the purchasing power of the country, in this case, to put GDP on the same playing field as the U.S. dollar. Here, not every cost is adjusted for purchasing power, so it may not be a good indicator of economic impact.

GNI: GDP adjusted to include income the country earns as a result of Foreign Direct Investment. Because we are not looking at vaccinating Brazilians abroad, this is not a good measure of productivity.

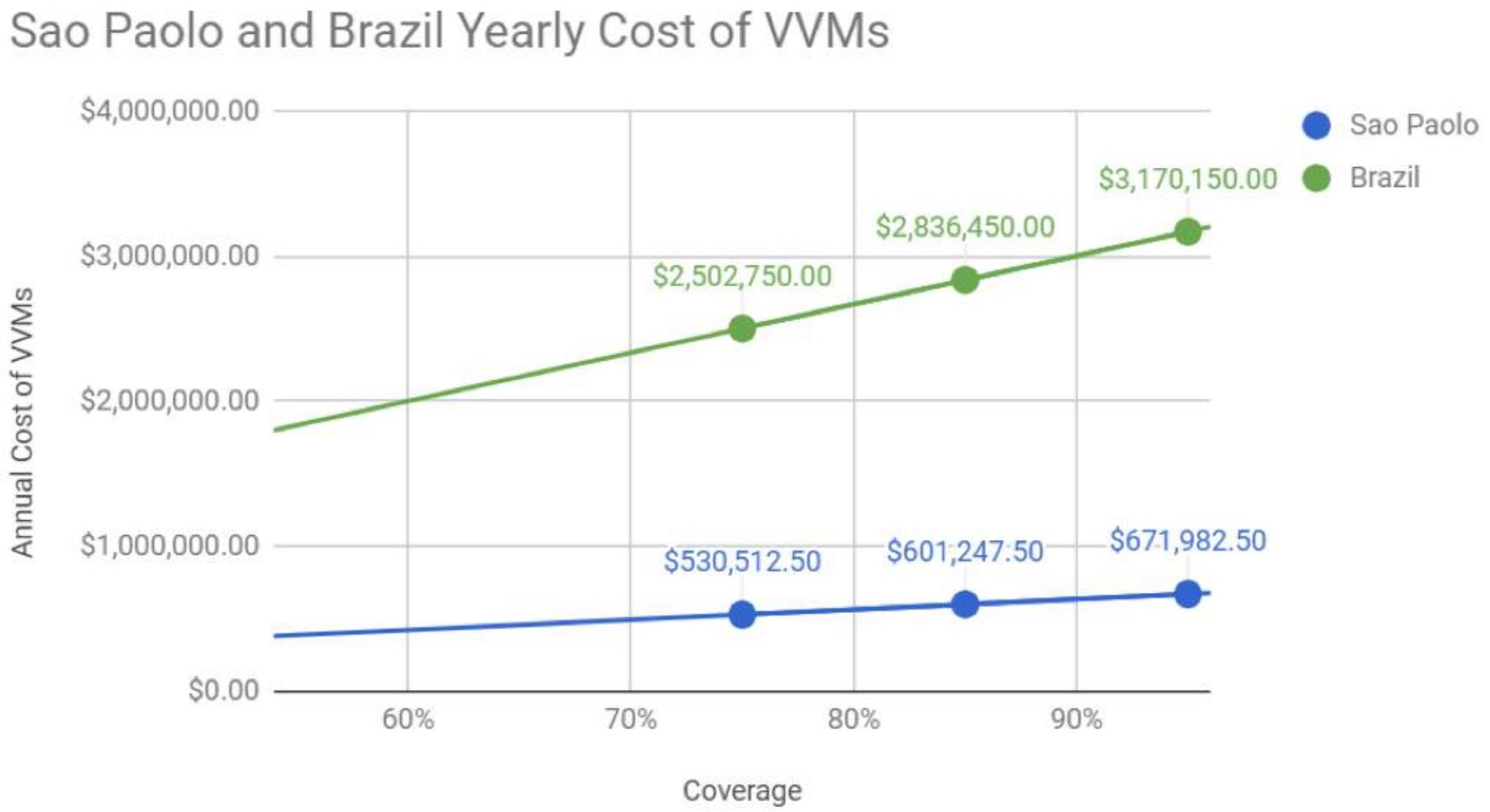
# VVM Implementation Costs

| # of vaccines per year in Brazil | Sao Paolo, 2019, 95% | 85% | 75% | Brazil, 95% | 85% | 75% |
|---|---|---|---|---|---|---|
| Each brazilian receives | 23 | | | 23 | | |
| Rounded to account for special circumstances | 25 | | | 25 | | |
| Divided by life expectancy of 75 years | 0.333333333 | | | 0.333333333 | | |
| Multiplied by population of Brazil | 15,050,000 | | | 71,000,000 | | |
| Multiplied by coverage rate | 14,297,500 | 12,792,500 | 11,287,500 | 67,450,000 | 60,350,000 | 53,250,000 |
| Multiplied by average yearly cost/vaccine | $ 16,209,883.87 | $ 14,503,580.30 | $ 12,797,276.74 | $ 76,471,877.39 | $ 68,422,206.09 | $ 60,372,534.78 |
| Multiplied by VVM cost | $ 16,881,866.37 | $ 15,104,827.80 | $ 13,327,789.24 | $ 79,642,027.39 | $ 71,258,656.09 | $ 62,875,284.78 |
| Difference | $ 671,982.50 | $ 601,247.50 | $ 530,512.50 | $ 3,170,150.00 | $ 2,836,450.00 | $ 2,502,750.00 |

Calculated using:

- Brazilian vaccination schedule
- Life expectancy estimates
- Population of Brazil (2018, estimated 2021)
- Estimated vaccination coverage rate (WHO)
- Average cost of vaccine (estimated, see appendix slide)
- VVM cost of $0.047 for an order of 4 million VVMs at a time

# Implementation Costs Based on Coverage



# Choosing a Labeling Machine

Estimated using Quadrel Pharmaceutical Labeling machine costs, each approximately $1.5 million

**Pharmaceutical Vial and Ampule Labeling System**

This technically advanced vial and ampule labeler is serialization-ready, designed specifically for the needs of tier 1 pharmaceutical companies. Features include laser imprinting of date and lot codes, vision system and full validation package. Additional features include Allen Bradley PLC control, PanelView color touchscreen, servo driven applicators.

**ProLine Inline Labeling System**

This is Quadrel's premium inline pharmaceutical labeling system and features environmentally protected overhead controls, full vision system, Allen Bradley PLC, PanelView color touchscreen, as well as servo driven applicators and product handling. Additional features include internationally compliant guarding and stainless steel construction.

**High-Speed Vial Labeling System**

This custom pharmaceutical labeling system features rotary infeed tray and product accumulation system. It is designed specifically for small diameter glass vials and ampules at speeds up to 300 products per minute. Additional features include full vision system, Allen Bradley PLC control, PanelView color touchscreen and validation package.

Each machine pastes at a rate of 300/minute
Assumed 8 hour workday, 5 days/week, 50 weeks/year = 36,000,000 labels attached/year
Labels needed according to VVM implementation calculations: 14.3 million for first 3 years

# Unit cost of vaccines

| | |
|---|---|
| Hep B | 0.3264 |
| HIB | 2.05 |
| HPV | 9.8 |
| MMR | 0.6 |
| Pnuemo | 6.8 |
| Rota | 6.5 |
| Avg vaccine cost per year | 1.133757 |

Source: PAHO

# Country Matrix

| | Disease Risk | Cold Chain | Healthcare system | Pop. | Economic outlook |
|---|---|---|---|---|---|
| **Paraguay** | Intermediate | -largely reliable | #57 | 1.28% | 4.5% |
| **Brazil** | High | -no temp monitoring; hard-to-reach remote areas | #125 | 0.79% | 2.95% |
| **Chile** | Intermediate | -limited capacity; high staff turnover | #33 | 0.81% | 2.3% |
| **Venezuela** | High | -limited capacity; insufficient temp. monitoring | #54 | 1.29% | 741% |
| **Source** | CIA World Factbook | European Commision Food and Veterinary Office; Unicef, PATH, USAID | WHO | World Pop. Review | Trading Economics (Jan. 2018) |

# Brazil Disease Burdens

| **Disease** | **DALYs (2016 annual)** |
|---|---|
| Hep B | 35,008 |
| HPV~ Cervical Cancer | 267,801 |
| Yellow Fever | 304 (will rise with outbreak) |

DALYs: sum of years of life lost due to premature mortality and years lost to disability (IHME)

# Vaccine stability matrix (PAHO)

| | |
|---|---|
| Most sensitive | OPV |
| | Measles, MR, MMR |
| | DTP, **DTP-Hep** B, DTP-Hib, **YF** |
| | BCG, **HPV** |
| | HIB, DT |
| Least sensitive | Td,TT, JE |

# Hep B- savings estimate

Est. cost of chronic hepatitis B virus for Brazilian unified health system in 2005:

- Hep B virus places large financial burden on Brazilian health system

| CHBV | 1st stage | 2nd stage | 3rd stage | 4th stage |
|---|---|---|---|---|
| Cost (US $) | $392 | $496 | $8809 | **$34,948** |

15%-40% may develop complications of hepatitis B virus (HBV) infection, including cirrhosis, decompensation, and hepatocellular carcinoma (HCC)

# Why EPI?

## Benefit of family-vaccination:

- Establishment of herd immunity at family scale

## Benefit of diseases targeted by “newer” vaccines:

- These are diseases which can have long-term sequelae
  - Human Papillomavirus → Cervical cancer
  - Hepatitis B → chronic Hep B & liver complications

# Lives Saved

158,000 lives / 35 countries = 4514 / 9 years = 502*5 years = 2508

lives saved between 2019-2023 * Brazil GDP (8,649.95) = $21.7 million