Large buyer Coordinated demand visibility update

23 July 2018
IAS
The Netherlands
Global Fund, PEPFAR and Government of South Africa are working together to improve the consolidated demand outlook

<table>
<thead>
<tr>
<th>What we will do</th>
<th>What we will not do together</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Coordinated approach</strong> and messages</td>
<td><strong>Long-term agreements</strong> with manufacturers</td>
</tr>
<tr>
<td><strong>Synergistic</strong> strategies</td>
<td><strong>Selection of suppliers</strong> and demand allocation</td>
</tr>
<tr>
<td><strong>Direct engagement</strong> with suppliers &amp; supplier visits (sometimes)</td>
<td><strong>Execution of purchase orders</strong></td>
</tr>
<tr>
<td>Align on <strong>key supplier performance metrics</strong></td>
<td>We will not manage actual <strong>supplier performance jointly</strong></td>
</tr>
<tr>
<td>Sharing of <strong>synthesized market intelligence</strong> and general supplier performance</td>
<td>Managing <strong>overall supplier performance</strong> (Price, lead-time, delivery etc.)</td>
</tr>
<tr>
<td><strong>Sharing information</strong> (without providing confidential / sensitive information)</td>
<td></td>
</tr>
<tr>
<td>Providing <strong>improved demand visibility</strong></td>
<td></td>
</tr>
</tbody>
</table>
Increased dialogue between buyers & sellers over the last 20 months

Update @ July 2018

- All updates posted @ https://www.theglobalfund.org/en/sourcing-management/health-products/antiretrovirals/
- Other actions being adopted by buyers and sellers
  - A number of procurement channels considering performance metrics, Framework contracts and moving away from frequent spot tenders
  - Big funders/buyers committed to further strengthen partnership and improve on demand management
**Demand & order management**

- Improve certainty on the time dimension; reduced volatility (smoothen demand)
- Aligned messages to programs on the benefits of better planning; incentivize good planning
- Expand scope and discuss forecasts/deviations to improve “trust in the forecast”
- Streamline administrative process and reduce bottlenecks to reduce inventory & write-offs
- Stronger coordination amongst funders and buyers
- Improved and more timely demand planning at the country level

**Process & product lifecycle**

- Stable buyer/seller partnership and volume certainty to enable sustainable investment and to optimize process development, API sourcing, and production
- Early and continuous engagement especially on new products (buyer, seller, & programs)
- Optimize and harmonize product and packaging specifications
- Clear pathways for new products and new suppliers

**Performance**

- Buyers to align on performance metrics
- Incentivize continuous improvement
- Articulate the cost of poor performance and encourage procurement channels to consider factors beyond price especially performance
## Large ARV Buyers and Sellers Forum November 2017
### Breakout Sessions notes: Value for Money

### Topics discussed

#### Sourcing/ Supplier Management
- Reduce packaging and markings while linking with regulations
- Bring services closer to customers to reduces freight cost and allow for smaller batch sizes

#### Demand Management
- Deliver large orders in smaller consignments
- Demand planning should be a 2-way communication
- Execute volume commitments

#### Process & product lifecycle
- Enable continuous production through smoother more regular orders
- Leverage technology to use bar-coding
- Implement packaging efficiencies to reduce shipping costs
- Harmonize labelling requirements by aligning global, regional and national approaches
- Encourage swifter regulatory approvals to implement manufacturing and supply efficiencies
- Alignment of regulatory processes to be able to while bringing more countries into regional harmonization efforts
- Reduce pill size through process technologies and new molecules

#### Supply chain optimization
- Invest in local packaging
- Freight optimization
- Ship bulk drugs to country and execute filling and labeling in country

#### Improve forecasting
- For manufacturers it is all about lead time
- Big buyers do the forecasts

#### Optimize packaging & labeling
- Single standard or put in barcodes that can be accessed in country (and link to reporting mechanism).
- Inserts can be printed locally or made directly available to patient via their cell phone
- Remove inserts and remove cartons (and standardize)
- Doing away with the cartons – low hanging fruit
<table>
<thead>
<tr>
<th>Topics discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sourcing closer to demand</strong></td>
</tr>
<tr>
<td>▪ For a local manufacturing level – capex is an issue. The length of tender or finding innovative finance mechanisms or an operational model that can spread the burden of this risk</td>
</tr>
<tr>
<td><strong>Optimize storage</strong></td>
</tr>
<tr>
<td>▪ In a large country – placing larger orders is a struggle – instead deliver it in monthly/quarterly batches; formulate the order to be delivered in batches</td>
</tr>
<tr>
<td>▪ Leverage technology: bar coding and automatic ordering</td>
</tr>
<tr>
<td>▪ Leverage cell phone technology for pharmacovigilance</td>
</tr>
<tr>
<td>▪ Better leverage regional warehouses</td>
</tr>
<tr>
<td>▪ Redefine shelf life requirements to not hamper longer shelf life products and emergency deliveries.</td>
</tr>
<tr>
<td>▪ suppliers recommend using months of until expiry instead of a percentage of RSL.</td>
</tr>
<tr>
<td>▪ Multi-month packs</td>
</tr>
<tr>
<td>▪ Establish market early warning system for suppliers</td>
</tr>
</tbody>
</table>

**Other**

- Establish market early warning system for suppliers.
### Topics discussed

#### Information needed
- Need also more disaggregated demand information including company specific allocations from more buyers
- Demand visibility should be shared for the next level up in the supply chain (e.g. FPP to provide visibility to API etc.)

#### Accuracy
- +/- 20% in forecasts is manageable

#### Impacts of poor demand
- Substantive uncertainty of demand with order late or not visible/predictable creates significant peaks and troughs in demand
- Manufacturing inefficiency where unutilized capacity and stop/start takes time to restart/respond - or may be allocated to other products
- Respond to poor demand management by holding inventory – so works in terms of responsiveness for buyers – even though not at an insignificant cost of capital and expiry risk (especially with high remaining shelf life requirements)
- Challenges compounded up the supply chain and longer lead-times for sourcing of APIs and Key Starting Materials (KSM)
Caveats and Limitations

**Conservative estimates** based on currently confirmed demand
Prepared based on **data currently available** to The Global Fund, Government of South Africa, Kenya and PEPFAR

- Kenya data may include PEPFAR, Global Fund and Government of Kenya demand
- PEPFAR data is inclusive of both USAID and CDC demand

**Preliminary estimates for discussion only** – and not final purchase commitments

**May not yet fully capture lead times** between order placement at manufacturer and in-country delivery
Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, million

- Malawi
- Tanzania
- Zimbabwe
- Ethiopia
- Zambia
- Kenya
- Mozambique
- Nigeria
- Uganda
- Cote d’Ivoire

- TLE/TEE
- LZN (adult)
- LZN (pediatric)
- Lpv/r (adult)
- ATV/r
- LZ (adult)
- EFV 600
- NVP 200
- TLD
- DTG 50mg

DISCLAIMER: This is an initial version of the forecast, and may contain inaccuracies. These slides contain a conservative estimate for demand management between the three programs. As such, there may be future volumes not yet financially committed or confirmed.

## TLE 600, TLE 400, and TEE – Consolidated Demand Forecast Outlook

### Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, million

<table>
<thead>
<tr>
<th>Country</th>
<th>Q3 2018</th>
<th>Q4 2018</th>
<th>Q1 2019</th>
<th>Q2 2019</th>
<th>Q3 2019</th>
<th>Q4 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malawi</td>
<td>5</td>
<td>12</td>
<td>13</td>
<td>8</td>
<td>13</td>
<td>7</td>
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<tr>
<td>Tanzania</td>
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<td>2</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>28</td>
<td>28</td>
<td>28</td>
<td>19</td>
<td>19</td>
<td>11</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>11</td>
<td>10</td>
<td>10</td>
<td>9</td>
<td>13</td>
<td>2</td>
</tr>
<tr>
<td>Zambia</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Kenya</td>
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<td>Mozambique</td>
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<td>Nigeria</td>
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<td>Uganda</td>
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<tr>
<td>Cote d'Ivoire</td>
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</tbody>
</table>

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**SOURCE:** PEPFAR (USAID and CDC), Kenya, Government of South Africa, The Global Fund

*Forecast at mid-July*
TLD – Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q2 2018-Q3 2019, Number of packs, million

- PEPFAR
- Kenya
- Republic of South Africa
- The Global Fund

- Malawi
- Tanzania
- Zimbabwe
- Ethiopia
- Zambia
- Kenya
- Mozambique
- Nigeria
- Uganda
- Cote d'Ivoire

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DTG 50mg – Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, thousands

- PEPFAR
- Kenya
- Republic of South Africa
- The Global Fund

Malawi
Tanzania
Zimbabwe
Ethiopia
Zambia
Kenya
Mozambique
Nigeria
Uganda
Cote d'Ivoire

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## LZN (Adult) – Consolidated Demand Forecast Outlook

**Overall ARV Demand Outlook**
Q3 2018-Q4 2019, Number of packs, thousands

<table>
<thead>
<tr>
<th></th>
<th>PEPFAR</th>
<th>Kenya</th>
<th>The Global Fund</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3 2018</td>
<td>839</td>
<td>593</td>
<td>1,432</td>
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<tr>
<td>Q4 2018</td>
<td>970</td>
<td>590</td>
<td>1,915</td>
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<tr>
<td>Q1 2019</td>
<td>2,443</td>
<td>1,915</td>
<td>513</td>
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<tr>
<td>Q2 2019</td>
<td>667</td>
<td>377</td>
<td>15</td>
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<tr>
<td>Q3 2019</td>
<td>983</td>
<td>829</td>
<td>983</td>
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<tr>
<td>Q4 2019</td>
<td>1,209</td>
<td>1,125</td>
<td>14</td>
</tr>
</tbody>
</table>

**Programs:**
- Malawi
- Tanzania
- Zimbabwe
- Ethiopia
- Zambia
- Kenya
- Mozambique
- Nigeria
- Uganda
- Cote d'Ivoire

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**SOURCE:** PEPFAR (USAID and CDC), Kenya, Government of South Africa, The Global Fund
LZN (Pediatric) – Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, thousands

PEPFAR  Kenya  The Global Fund

Malawi  Tanzania  Zimbabwe  Ethiopia  Zambia  Kenya  Mozambique  Nigeria  Uganda  Cote d'Ivoire

Q3 2018  Q4 2018  Q1 2019  Q2 2019  Q3 2019  Q4 2019

1,180  1,368
354  275  738
324  1,041  49
227  52  637
52  52  52  48
52  52  738
45  143  395
52  34  295
774  1,180

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LPV/r (adult) – Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, thousands

<table>
<thead>
<tr>
<th>Quarter</th>
<th>PEPFAR</th>
<th>Kenya</th>
<th>Republic of South Africa</th>
<th>The Global Fund</th>
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</thead>
<tbody>
<tr>
<td>Q3 2018</td>
<td>1,005</td>
<td>198</td>
<td>124</td>
<td>499</td>
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<td></td>
<td></td>
<td>184</td>
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<td></td>
</tr>
<tr>
<td>Q4 2018</td>
<td>1,110</td>
<td>399</td>
<td>80</td>
<td>539</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Q1 2019</td>
<td>920</td>
<td>144</td>
<td>46</td>
<td>578</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td>Q2 2019</td>
<td>462</td>
<td>42</td>
<td>28</td>
<td>267</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Q3 2019</td>
<td>405</td>
<td>42</td>
<td>18</td>
<td>253</td>
</tr>
<tr>
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</tr>
<tr>
<td>Q4 2019</td>
<td>398</td>
<td>43</td>
<td>16</td>
<td>236</td>
</tr>
</tbody>
</table>

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ATV/r – Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q3 2018-Q 2019, Number of packs, thousands

- PEPFAR
- Kenya
- The Global Fund

<table>
<thead>
<tr>
<th></th>
<th>Q3 2018</th>
<th>Q4 2018</th>
<th>Q1 2019</th>
<th>Q2 2019</th>
<th>Q3 2019</th>
<th>Q4 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEPFAR</td>
<td>708</td>
<td>385</td>
<td>149</td>
<td>459</td>
<td>386</td>
<td>56</td>
</tr>
<tr>
<td>Kenya</td>
<td>106</td>
<td>101</td>
<td>222</td>
<td>51</td>
<td>54</td>
<td>56</td>
</tr>
<tr>
<td>The Global Fund</td>
<td>126</td>
<td>122</td>
<td>357</td>
<td>249</td>
<td>64</td>
<td>38</td>
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</tbody>
</table>

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Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, thousands

TL – Consolidated Demand Forecast Outlook

Consolidated Demand Forecast Outlook

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LZ (adult) – Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, thousands

PEPFAR
Kenya
Republic of South Africa
The Global Fund

- Malawi
- Tanzania
- Zimbabwe
- Ethiopia
- Zambia
- Kenya
- Mozambique
- Nigeria
- Uganda
- Cote d'Ivoire

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EFV 600 – Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, thousands

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NVP 200 – Consolidated Demand Forecast Outlook

Overall ARV Demand Outlook
Q3 2018-Q4 2019, Number of packs, thousands

PEPFAR
Kenya
Republic of South Africa
The Global Fund

Malawi
Tanzania
Zimbabwe
Ethiopia
Zambia
Kenya
Mozambique
Nigeria
Uganda
Cote d'Ivoire

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TLD TRANSITION & SUPPLY PLAN UPDATE
First Line ARV Fixed Dose Combinations, PEPFAR
Millions of Packs Ordered as of July 5, 2018*

2006: Patients transitioned off d4T 40

2010: TLE and LZN recommended first line for patients starting ART*

2013: EFV with TL or TE recommended preferred first line for patients starting ART*

2016: DTG with TL or TE recommended as alt first line*

2017: FDA approves TLD (Aug)

LSN  LZN  TEE  TLE  TLE400  TLD

Routine Use of TLD as Second-Line ART

Opportunity to simultaneously use TLD as second-line ART

Weighing potential advantages of TLD over Protease Inhibitor (PI)-based second-line ART against potential concerns
Where does DTG currently stand in National Treatment Guidelines?
DTG Rollout among Women Treatment Populations

Equity

Variation in definition of childbearing age

More nuanced approaches

Consistent contraception?
## Concerns for Adolescents

<table>
<thead>
<tr>
<th>Countries That Do Not Include Adolescent Ages within CBA Range</th>
<th>Adolescent Age Range</th>
<th>CBA Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burundi</td>
<td>10-18</td>
<td>15-49</td>
</tr>
<tr>
<td>DRC</td>
<td>10-19</td>
<td>14-49</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>10-19</td>
<td>15-49</td>
</tr>
<tr>
<td>Haiti</td>
<td>10-14</td>
<td>15-49</td>
</tr>
<tr>
<td>eSwatini</td>
<td>10-19</td>
<td>18-49</td>
</tr>
<tr>
<td>Uganda</td>
<td>10-19</td>
<td>15-49</td>
</tr>
</tbody>
</table>
TLD Firm Orders
LZN vs. TLE vs. TLD Consumption
July 2018 – July 2021

Does not include: Cameroon, Kenya, Namibia, Lesotho, Botswana, South Africa
## Timeline for TLD Transition

<table>
<thead>
<tr>
<th>Country</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rwanda</td>
<td></td>
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<tr>
<td>Zambia</td>
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<tr>
<td>Nigeria</td>
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<tr>
<td>Uganda-JMS</td>
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<tr>
<td>Uganda-MAUL</td>
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<td></td>
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<td>Uganda-NMS</td>
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<tr>
<td>Haiti</td>
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<td></td>
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<tr>
<td>Ukraine</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>eSwatini</td>
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<tr>
<td>Botswana</td>
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<td>Mozambique</td>
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<td>Tanzania</td>
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<td>Malawi</td>
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<td>Cote d'Ivoire</td>
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<td>Burundi</td>
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<td>DRC</td>
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<tr>
<td>Ethiopia</td>
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<td></td>
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<tr>
<td>South Africa</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Zimbabwe</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Cameroon</td>
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<tr>
<td>Lesotho</td>
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<tr>
<td>Vietnam</td>
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<td></td>
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<tr>
<td>South Sudan</td>
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<td></td>
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<tr>
<td>Namibia</td>
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</tbody>
</table>

New Patients Only
Timeline of South Africa Transition

Dec 2017: Minister of Health and Cabinet announce DTG introduction will be in April 2018
Jan 2018: Guidelines “finalised”
End Jan 2018: Clear above NOT possible with current tender processes
March 2018: SAHPRA refused to register ANY TLD combination
April 2018: Clarifying tender processes, working with SAHPRA
July 2018: New submissions of dossiers
July 2018: Tender planned release 17 August, close mid-Sept
April 2019 Introduction?

Thanks Francois Venter
Changes in D4T, AZT & TDF use – often FAST

Between 2 to 4 million people using AZT containing regimen in 2012

WHO AMDS database, 2014, (preliminary data)
South Africa possible scenarios post-NTD signal

Stay with TEE (or TLE) or go with DTG (with small number on TLE)
Or hybrid – messy, but may be only way forward
Implement observational cohorts urgently (see later)

Thanks Francois Venter
Other Pharmaceutical Matters

✓ PEPFAR ARV and Pharmaceutical Formulations:

✓ Research, Regulatory, and Procurement Priorities
Other Pharmaceutical Matters

✓ Dolutegravir pediatric formulations

✓ Sulfamethoxazole/trimethoprim/isoniazid/pyridoxine
Thank You!