

Oxytocin in Uniject – March 2007 Update

Soon Available in Argentina and India

Can a Vaccine Technology Alleviate
Many Cold Chain Concerns?



PATH's HealthTech Program

Involvement in Oxytocin in Uniject

- Encourage/entice pharmaceutical companies to adopt Uniject for Oxytocin and other essential drugs
- Currently working with BIOL of Argentina and Gland of India
- Key Objectives
 - Provide supply for evaluations
 - Two companies qualified to supply Oxytocin in Uniject to international agencies



Oxytocin in Uniject: Progress with BIOL of Argentina

Brief History:

- Oxytocin in Uniject Stuck in this loop up through April 2005
- Moved into focused development collaboration with BIOL in Spring 2005
- Stability study initiation delayed until March 2006

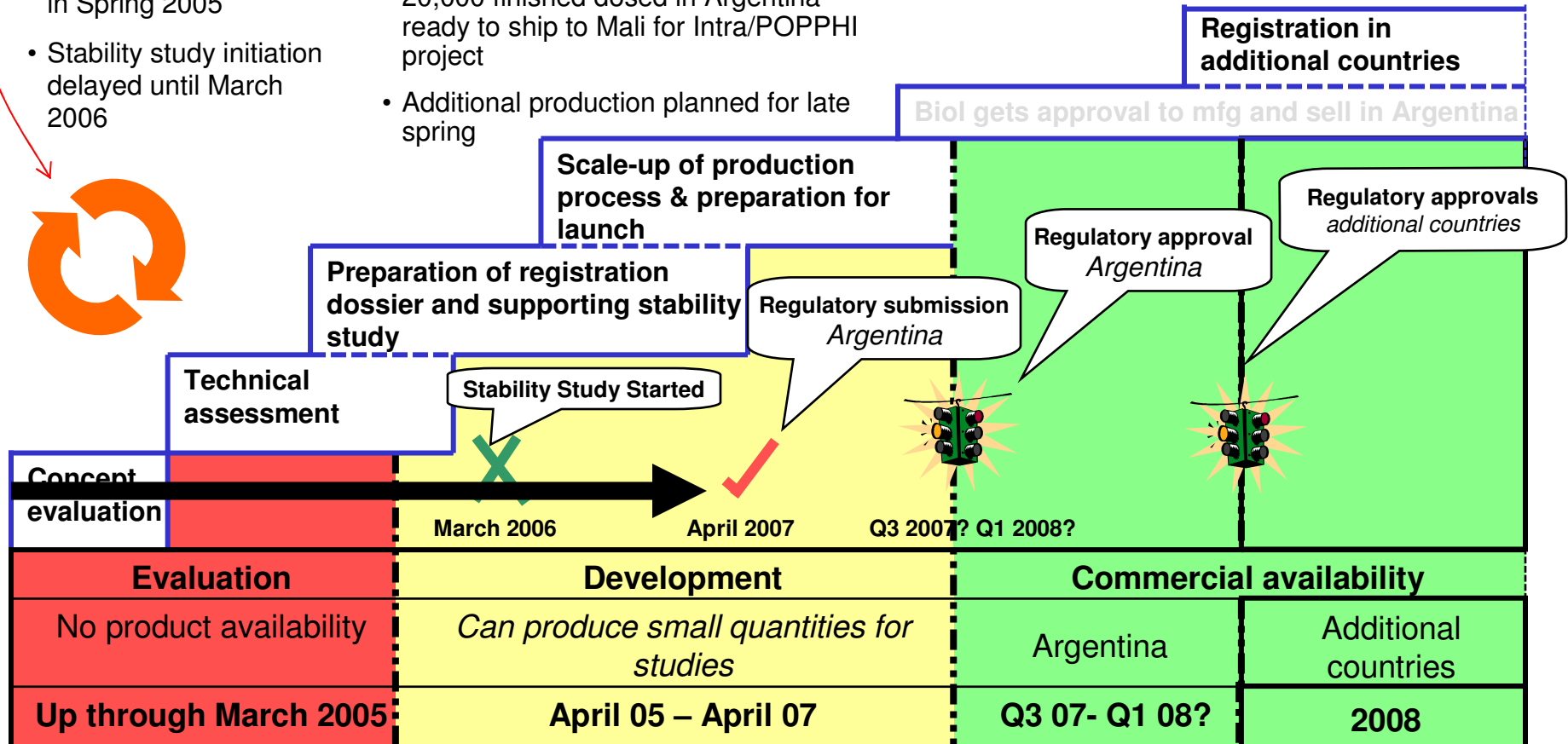


Current Status:

- 9 months of stability study completed January 07 with positive results
 - Excellent stability at 2 – 8* c
 - Potential stability at 25* c
- Key technical issue resolved
- 20,000 finished dosed in Argentina ready to ship to Mali for Intra/POPHI project
- Additional production planned for late spring

Key Next Steps:

- BIOL registration dossier submission
- Argentine registration for commercial sale
- Shift into routine production and supply



Gland Pharma of India Current Status

- Completed initial stability study with positive results in Fall 06
- Received Indian Drugs Controller Approval for local sale in December 06
- Larger scale stability study June 07
- International dossier ready mid 2008



Oxytocin in Uniject Field Use Plans

- Mali in 2007 (Intrah and POPPHI)
- Argentina in 2007 (Tulane and IECS)
- India 2007 or 2008 (ICMR, PATH)
- South Africa 2007 or 2008 (PATH)
- Likely more as product becomes available



Potential Supply to UN Agencies (UNFPA, UNICEF, etc)

- Each producer must be evaluated for quality before being offered opportunity to sell to UN agencies
- This vendor qualification process is product (Uniject/Oxytocin) and producer specific
- **BIOL and Gland Pharma can not request UN agency vendor qualification for Oxytocin/Uniject until after they have home country FDA approval**
- Realistic scenario—UN vendor qualification process during 2008



Oxytocin in Uniject Summary

- Commercially available soon—possibly this year, definitely next year
- Supply for field evaluation now possible in Argentina and India
- Price range estimates of \$.40 - \$.60 per dose still holding... (especially when sales volume reaches 1 million+ annual units)



Yes, its real!

OXYTOCINE (10 UI/ml)
Solution injectable d'oxytocine de 1 ml (IM) - BD Uniject™ Seringue
1 ml contient la solution d'oxytocine préparée conformément à l'USP (pharmacopée des États-Unis).
Pour usage intramusculaire uniquement.

POUR USAGE NON COMMERCIAL DESTINÉ À L'UTILISATION DANS LE CADRE DU PROJET PILOTE
POPPHI-INTRAHEALTH MATRONE UNIQUEMENT

HEATmarker® VVM
Indicateur Temps-Température

Fabriqué par
Instituto Biológico
Argentino SAIC (BIOL),
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ARGENTINE



Utiliser uniquement si le cadre HeatMarker est plus clair que l'anneau extérieur.
Conservation recommandée entre 2°C et 8°C.
La conservation à température ambiante est autorisée, mais peut avancer la date d'expiration du produit. Contrôler le HeatMarker et utiliser suivant les indications. Ne pas conserver ou transporter au-delà de 37°C.

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Lot: FT001 Date de lab.: Jan. 2007 Date d'exp.: Déc. 2007



Vaccine Vial Monitors for Oxytocin



Can this proven vaccine technology now help us manage Oxytocin cold chain storage issues?

March 2007 POPPHI WG Meeting

What is a VVM? (or TTI)

ভ্যাকসিন ভায়াল মনিটর-টি (ভি ভি এম) লক্ষ্য করুন

- ফিতরের চকুসোপের রং বাইরের কৃত্রিম রং-এর সাথে মিশে গেলে অথবা কৃত্রিম রং-এর চেয়ে গাঢ় হলে **ভায়ালটি ব্যবহার করবেন না।**
- মেয়াদকাল উত্তীর্ণ হবার আগেই ভায়াল ব্যবহার করুন।

□	✓
□	✓
●	✗
■	✗

- Chemical time and temperature cumulative exposure indicator
- Rate of color change calibrated for different vaccine stability profiles
- Now it widespread use for UN procured vaccines

Successful use of VVMs

Polio eradication efforts



©UNICEF



©World Health Organization:



PATH

March 2007 POPPHI WG Meeting



Successful use of VVMs

Outreach with hepatitis B and tetanus toxoid vaccines



PATH/Carib Nelson



PATH/Carib Nelson



PATH/Glenn Austin

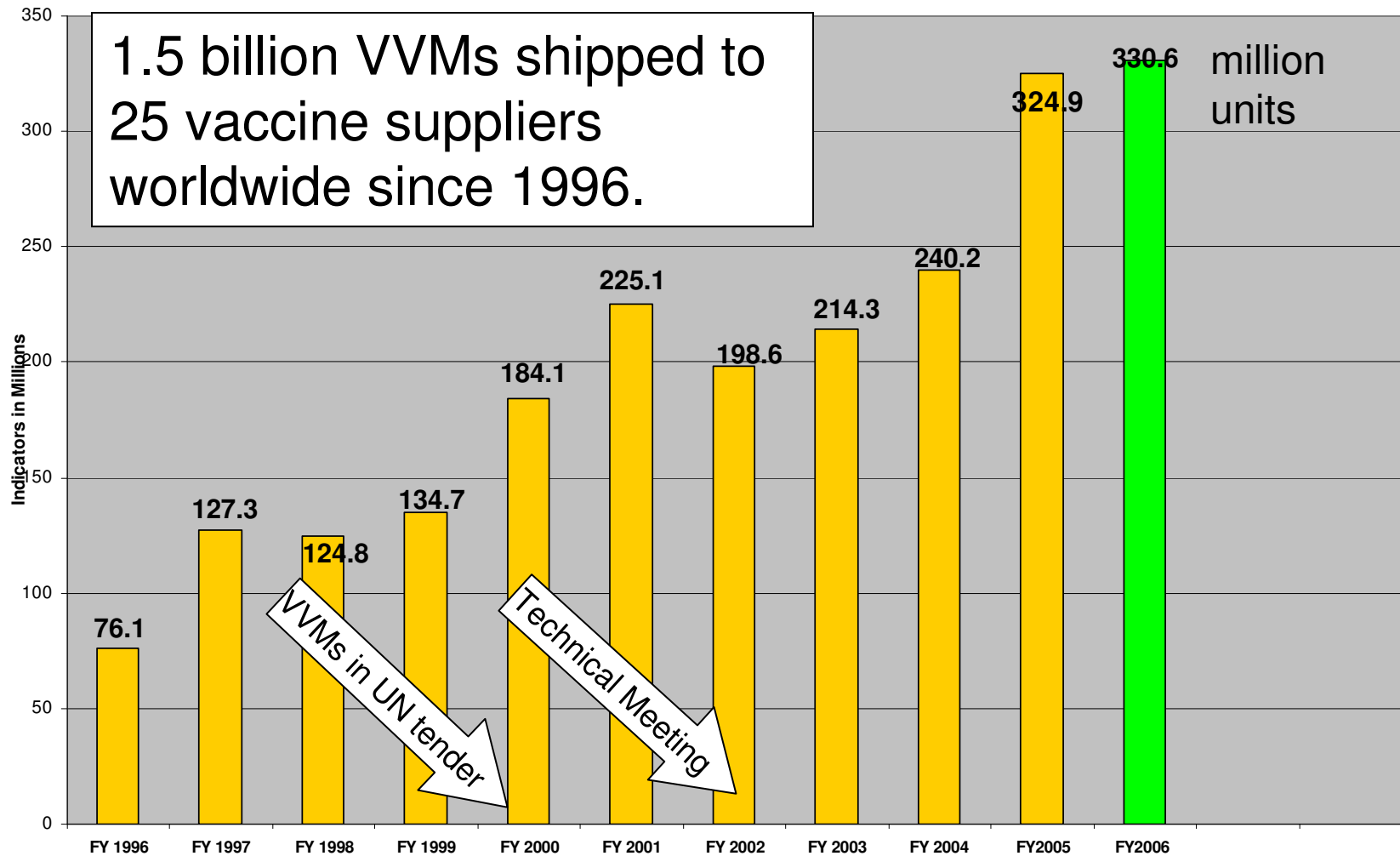


PATH/Jhonky Aliman



Photo: UNICEF/HQ020267/Giacomo Pirozzi

Global VVM distribution 1996–2006

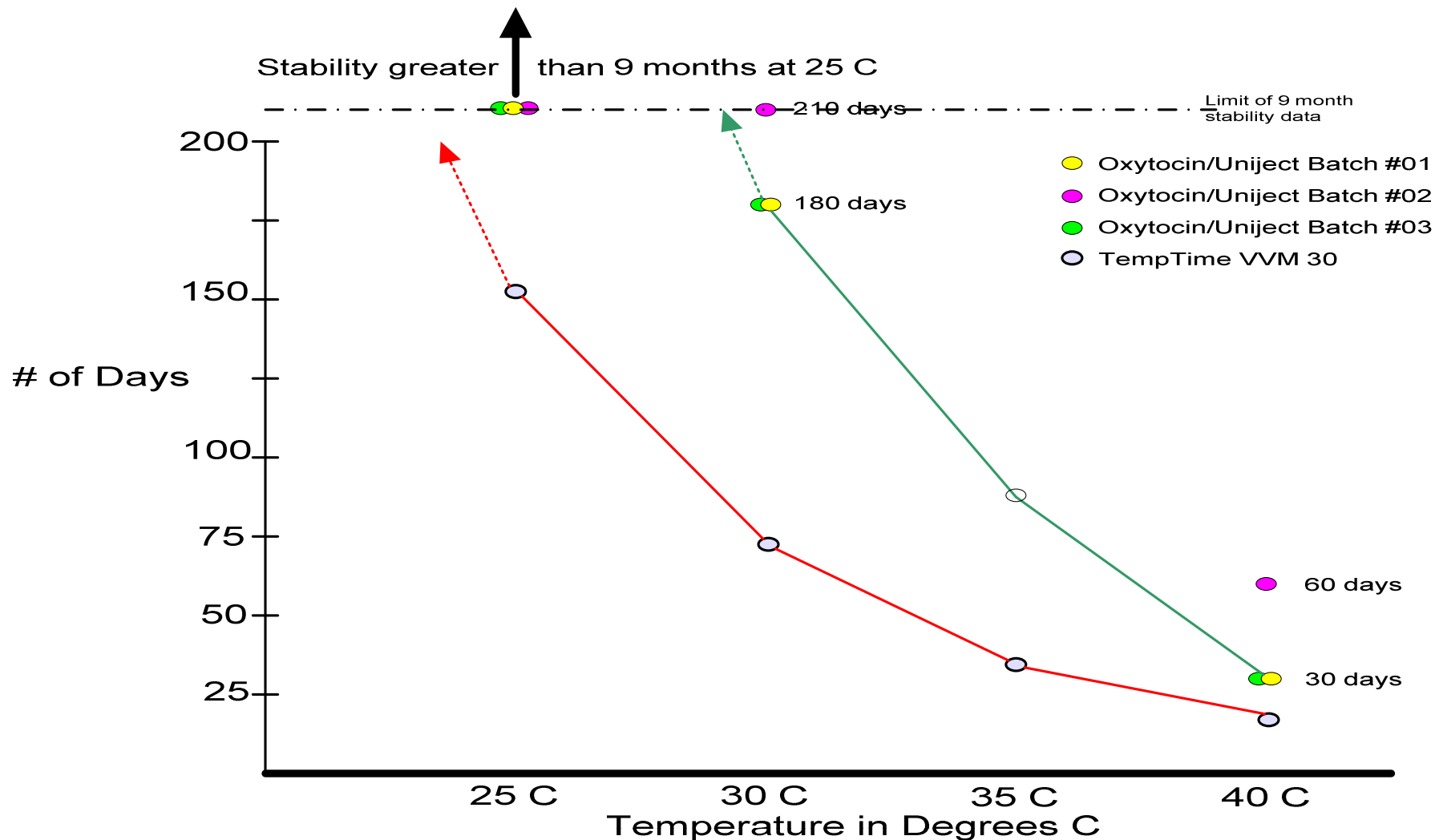


VVM's and Oxytocin--possibilities

- Improvement in overall quality assurance of programs—only effective oxytocin would be used
- Flexible cold chain management—oxytocin could move in and out of cold chain, cool chain, room temperature
- Longer “out of cold chain” periods possible than with other approaches



VVM 30 Endpoints & BIOL Oxytocin in Uniject Stability



VVM's and Oxytocin—a recently identified lucky break

- One of the already formulated VVM's (VVM 30) is can be immediately put to use with BIOL oxytocin
- TempTime Inc (producer of VVM's) has agreed to provide no-cost product for all planned field evaluations
- BIOL will now integrate into their Ocytocin in Uniject product



VVM's and Oxytocin—reality check

- Could add \$.06-\$.10 to cost per dose (if VVM used on every dose)
- Must be accompanied with training on many levels (health workers, stock managers, policy makers)
- Best if critical mass of use can be achieved
- Requires oxytocin producer cooperation and investment



VVM's and Oxytocin—next steps

- Will be used on Oxytocin in Uniject on evaluation basis

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- Could be considered for a coordinated “push & pull” by our community

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