Agenda

INTRODUCTION
17:30-17:40
• Welcome and objectives
• Status Quo of non-adherence data-tracking

CASE STUDIES
17:40-18:00
• Examples of successfully implemented adherence-based tracking studies: ECOS, SMART & STAR

REAL WORLD APPLICATIONS
18:00-18:15
• Discuss how adherence-tracking can be implemented in LatAm to improve outcomes

DISCUSSION
18:15-18:30
• Questions for the audience
Today, the session will be led by three speakers.

SANDEEP DUTTAGUPTA, PhD  
Vice President, Emerging Markets  
CBPartners

DIEGO GUARIN, MD MPH MA  
Senior Director, HEOR & HTA Strategy  
MERCK-SORONO

MIGUEL MARTIN de BUSTAMANTE  
Senior Associate, Lead LatAm Center of Excellence  
CBPartners

The objective of this session is the discuss how patient adherence tracking can be leveraged as a source of real world evidence.

SESSION OBJECTIVES

- Provide an overview of the different mechanisms to track patient adherence
- Review three case studies of cloud-enabled data collection that have been implemented in real life
- Discuss how cloud-enabled data collection systems can be used in LatAm to track adherence and real world outcomes
Non-adherence is a major health cost, with numerous studies indicating that non-adherence rates lead to poor outcomes, high costs and lost productivity.

**THE PROBLEM OF NON-ADHERENCE**
- Non-response and poor adherence are critical issues, which can be costly for the healthcare system.
- It is expected that 13 – 72% of patients are non-adherent to their prescription.
- In EU, non-adherence is predicted to cause 194,500 deaths each year, costing up to EUR 1.25 billion.

**BENEFITS OF ADDRESSING NON-ADHERENCE**
- Improvement in patient adherence would positively impact the wider health economy by improving health population outcomes, enhancing quality of life and reducing per capita costs.

A successful patient adherence program has to be patient-centric and multi-factorial, including patient education and tracking amongst others.
Data collection methods for monitoring patient adherence have evolved from self-reported surveys to cloud-based electronic monitoring.

**PATIENT ADHERENCE**

**DATA COLLECTION METHODS**

<table>
<thead>
<tr>
<th>METHOD</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SELF-REPORTED</strong></td>
<td>Adherence inferred from self-administered patient questionnaires</td>
</tr>
<tr>
<td><strong>PHYSICIAN-REPORTED</strong></td>
<td>Healthcare provider opinion based on interviews with patients and interpretation of outcomes</td>
</tr>
<tr>
<td><strong>PRESCRIPTION CLAIMS DATA</strong></td>
<td>Adherence inferred from the frequency with which a patient refills a prescription (i.e., MRP and PCD)</td>
</tr>
<tr>
<td><strong>PILL COUNT</strong></td>
<td>Measurement of the number of units that should have been ingested vs. the units that were ingested</td>
</tr>
<tr>
<td><strong>BIOCHEMICAL MARKERS</strong></td>
<td>Measurement of the drug or its metabolite concentration in body fluids</td>
</tr>
<tr>
<td><strong>ELECTRONIC ADHERENCE MONITORING</strong></td>
<td>Use of “smart” dispensing devices that can record information about the use of the medication and other adherence data</td>
</tr>
</tbody>
</table>

Not all pharmaceutical innovations require a new API; electronic monitors are an innovation which can improve health outcomes and convenience.

Image adapted from: The Many Faces of Innovation, ABPI, 2012

API: Active Pharmaceutical Ingredient
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Two real-life case studies demonstrate the ability and impact of leveraging technology to track patient adherence.

TECHNOLOGY-ENABLED PATIENT ADHERENCE
CASE STUDIES

GROWTH DEFICIENCY

MULTIPLE SCLEROSIS
EASYPOD connect is a secure online platform for monitoring adherence of patients who are prescribed SAIZEN and are using the EASYPOD auto-injector.

**EASYPOD CONNECT OVERVIEW**

**KEY FUNCTIONALITIES**

- Store adherence data from the EASYPOD auto-injector and outcomes data entered by the HCP
- Calculates adherence for the patient total dose administered and total number of injections
- Generates data reports and graphics
- Generates and sends injection and data upload reminders
- Monitors patient's treatment over time and with possibility to compare historical data

**EASYPOD CONNECT PLATFORM**

**ECOS is an observational study to evaluate the adherence and predictive factors in pediatric patients prescribed with SAIZEN.**

**ECOS OBSERVATIONAL STUDY**

**OBJECTIVE**

- **PRIMARY:** Evaluate the level of adherence of pediatric patients receiving SAIZEN via EASYPOD
- **SECONDARY:** Assessment of the impact of adherence on clinical outcomes, the concentrations of insulin-like growth factors and identification of factors that may influence adherence to treatment

**METHODOLOGY**

- **PATIENT POPULATION:** 1,972 children with growth hormone deficiency (65.7%), small for gestational age (15.0%) and Turner Syndrome (7.7%)
- **DESIGN:** multi-center, observational, prospective study carried out in 23 countries with a follow-up duration of up to 5 years, with interim analysis every year
- **DATA COLLECTED:**
  - From EASYPOD: adherence data
  - From HCP Notes: demographic, anthropometric and diagnostic data
- **DEFINITION OF ADHERENCE:**
  \[
  \text{ADHERENCE (\%)} = \frac{\# \text{ DAYS WITH INJECTION RECEIVED}}{\# \text{ DAYS WITH PLANNED INJECTION}}
  \]
The ECOS study results indicated patients receiving the auto-injector have better adherence than previously reported in other retrospective studies.

**ECOS OBSERVATIONAL STUDY RESULTS**

**ADHERENCE (%)**

<table>
<thead>
<tr>
<th></th>
<th>Median Adherence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHD, SGA &amp; TS</td>
<td>93%</td>
</tr>
</tbody>
</table>

Adherence levels prospectively measured with EASYPOD were higher than those previously reported in retrospective studies and were maintained over time.

**HEIGHT VELOCITY (CM / YEAR)**

<table>
<thead>
<tr>
<th></th>
<th>Height Velocity (CM / YEAR)</th>
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<tbody>
<tr>
<td>GHD</td>
<td>Δ 43%</td>
</tr>
<tr>
<td>SGA</td>
<td>Δ 41%</td>
</tr>
<tr>
<td>TS</td>
<td>Δ 9%</td>
</tr>
</tbody>
</table>

Investigator assessed height velocity increased 43%, 43% and 9% for GHD, SGA and TS, respectively, between baseline and readout.

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**MS DIALOG** is an online platform to track adherence and treatment outcomes of patients treated with REBISMART.

**REBISMART & MS DIALOG OVERVIEW**

**MS DIALOG PLATFORM**

- Electronic adherence monitoring
- Physiological remote patient monitoring
- Patient reported outcomes
- Physician (unblinded) & payer (blinded) portal
- Injection reminders
- Nurse portal
- Educational content
- Study to relate adherence to outcomes

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GHD: Growth Hormone Deficiency; SGA: Small Gestational Age; TS: Turner Syndrome

Davies et al. 2015

HCP: Healthcare Provider; MS: Multiple Sclerosis
SMART study assessed adherence to, and effectiveness and convenience of, treatment with REBISMART in patients with relapsing multiple sclerosis (RMS).

SMART OBSERVATIONAL STUDY

OBJECTIVE

- **PRIMARY:** Evaluate the level of adherence of RMS patients treated with REBISMART
- **SECONDARY:** Assess the impact of adherence on clinical outcomes and identification of factors that may influence adherence to treatment

METHODOLOGY

- **PATIENT POPULATION:** 912 RMS patients with Expanded Disability Status Scale score ≤ 6 that had received REBISMART for ≤ 6 weeks
- **DESIGN:** multi-center, observational, prospective study carried out in 14 EU countries with a follow-up duration of 1 year
- **DATA COLLECTED:**
  - Primary Endpoint: cumulative adherence to treatment
  - Secondary Endpoint: reasons for missed injections, proportion of patients who prematurely terminated treatment and reasons for ED, proportion of relapse-free patients, proportion of patients free of disease activity, mean number of relapses, serious AE and evaluation of the device
- **DEFINITION OF ADHERENCE:**

  \[ \text{ADHERENCE} \% = \frac{\# \text{ OF INJECTIONS ADMINISTERED}}{\# \text{ OF INJECTIONS EXPECTED}} \times 100 \]

Bayas et al. 2015

Patients with RMS self-injecting REBISMART had excellent adherence at 12 months, which was associated with good clinical outcomes.

SMART OBSERVATIONAL STUDY

RESULTS

<table>
<thead>
<tr>
<th>CUMULATIVE ADHERENCE (%)</th>
<th>ANNUALIZED RELAPSE RATE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>100%</strong></td>
<td>3.00</td>
</tr>
<tr>
<td><strong>50%</strong></td>
<td>2.00</td>
</tr>
<tr>
<td><strong>0%</strong></td>
<td>1.00</td>
</tr>
<tr>
<td><strong>97%</strong></td>
<td>0.30</td>
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</tbody>
</table>

Adequacy levels prospectively measured with REBISMART were very high and confirmed findings from previous 12-week user trials

Treatment with REBISMART was efficacious: 80% of patients were relapse-free at 12 months, mean ARR was significantly lower at 12 months and EDSS did not increase during the study period

MO.: Months; ARR: Annualized Relapse Rate; EDSS: Expanded Disability Status Scale; RMS: Relapsing Multiple Sclerosis

Bayas et al. 2015
STAR assessed the local tolerability, safety, disease activity and adherence of SC REBIF in patients with RMS.

STAR OBSERVATIONAL STUDY

OBJECTIVE

- PRIMARY: Assess the local tolerability of SC REBISMART in patients with RMS
- SECONDARY: Assess the impact of adherence on clinical outcomes and identification of factors that may influence adherence to treatment

METHODOLOGY

- PATIENT POPULATION: 251 RMS patients with Expanded Disability Status Scale score ≤ 6 that had received REBISMART for ≤ 6 weeks
- DESIGN: multi-center, observational, prospective study carried out in 6 EU countries with a follow-up duration of 1 year
- DATA COLLECTED:
  - Primary Endpoint: Proportion of patients with ISRs
  - Secondary Endpoint: general safety profile, adherence, effect of adherence on disease activity
- DEFINITION OF ADHERENCE:

  \[
  \text{ADHERENCE (\%) = \frac{\text{# OF INJECTIONS ADMINISTERED}}{\text{# OF INJECTIONS EXPECTED}} \times 100}
  \]

27.5% of patients experienced ISRs; this is equal to, or lower than, previously reported in CTs demonstrating the long-term good tolerability

Investigators rated the overall safety and tolerability of REBISMART to be excellent, very good or good is over 87% of the patients; AE accounted to 45% of discontinuations which compares favorably to previous studies (71.5%)
Results from the STAR study revealed the association between good adherence and lower ARR, confirming the importance of good adherence.

**STAR OBSERVATIONAL STUDY RESULTS**

### ADHERENCE

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<thead>
<tr>
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<th>6 MO.</th>
<th>12 MO.</th>
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<tr>
<td>% Patients with missed injections</td>
<td>20%</td>
<td>21%</td>
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</table>

Proportion of patients with missed injections since previous visit was similar at 6 and 12 months; most common reason for missed injection was "forgot to inject" (51.1%) 

### EFFECT OF ADHERENCE ON OUTCOMES

Patients with very good / good adherence had better treatment outcomes vs. those with fair / poor adherence: greater proportion of patients were relapse-free and ARR was significantly lower.

**MO.**: Months; **ARR**: Annualized Relapse Rate

**Other Real World Evidence studies using REBISMART:**

- Patient Preference and Adherence
  - Subcutaneous interferon β-1a administration by electronic auto-injector is associated with high adherence in patients with relapsing-remitting multiple sclerosis in a real-life study
  - Impact of adherence on subcutaneous interferon β-1a effectiveness administered by auto-injector in patients with multiple sclerosis

- Long-term adherence of patients with relapsing-remitting multiple sclerosis to subcutaneous self-injections of interferon β-1a using an electronic device: the RIVER study
  - Exploratory analysis of predictors of patient adherence to subcutaneous interferon beta-1a in multiple sclerosis: TRACER study
  - Patient adherence to and tolerability of self-administered interferon β-1a using an electronic auto-injector device: a multicentre, open-label, phase IV study
Case Studies illustrate the potential benefits of technology enabled patient-adherence programs.

**CASE STUDY TAKEAWAYS**

**OVERVIEW**

- **Electronic monitoring** provides an objective measure of adherence, therefore not subject to patient reporting errors.
- Patient adherence programs can be used to collect outcomes data, thus confirming the effect of therapy in real world setting.
- Program offers benefits to patients, payers and physicians:
  - Helps patients engage in the management of their disease.
  - Provides HCPS with easily accessible information to aid treatment management.
  - Provides payers aggregate views on patient outcomes and can support the negotiation of outcomes-based agreements.

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Adherence programs can provide benefits to patients, physicians and institutions; however, several hurdles have limited successful implementation.

**IMPLEMENTATION HURDLES**

- **SKEPTICISM OVER IMPACT OF NON-ADHERENCE**: Healthcare institution may question the importance of adherence, given the lack of locally validated clinical and economic consequences of non-adherence.

- **COSTS VS. COMPETITORS**: In highly commoditized spaces, with multiple therapeutic alternatives incremental value of the device may not be recognized.

- **FRAGMENTATION OF HEALTHCARE SYSTEMS**: Traditionally fragmented healthcare systems in LatAm, without integrated healthcare records and/or national registries.

- **DATA TRACKING & INFRASTRUCTURE**: Healthcare institutions often lack the internal infrastructure to systematically collect outcomes data.

- **IMPLEMENTATION BURDEN**: Potential concerns over the administrative burden associated with the implementation of the program.

- **LEGAL / COMPLIANCE**: Need to adhere to local data-sharing legislation, which may vary by country.

Combining the data-tracking with payer-specific applications that provide additional value may increase willingness to implement these schemes.

**POTENTIAL APPLICATIONS FROM TECHNOLOGY ENABLED PATIENT ADHERENCE PROGRAMS**

- **ADHERENCE-TRACKING**: provides real-life aggregate views on institutional patient adherence, which traditionally could only be obtained through randomized or observational CTs.

- **WASTAGE-TRACKING**: electronic monitoring devices can calculate real-life wastage, which traditionally could only be measured through research programs.

- **INTERVENTION MONITORING**: possibility to monitor the performance of clinics, and measure the impact of adherence on treatment outcomes (i.e., what is the success rate of the intervention?)

- **CONTRACT DESIGN**: data collected can be used to support the design of a tailored outcomes-based agreement.

This discussion will focus on how adherence-based contracts can be leveraged to align incentives of all stakeholders and pockets of opportunity where these may be implemented in LATAM.
Today we will review two potential based-adherence contracts; however, additional solutions may be explored based on payers’ concerns and priorities.

**ADHERENCE-BASED CONTRACTS OVERVIEW**

Today we will provide **two examples of adherence-based contracts** that could be considered: Pay-For-Performance based on Adherence & Coverage with Evidence Development

- **PAY FOR PERFORMANCE BASED ON ADHERENCE**
  - Agreement that enables a rebate for costs upon achieving / not achieving a defined clinical outcome target

- **COVERAGE WITH EVIDENCE DEVELOPMENT**
  - Funding is conditional on **additional data / evidence generation** through the patient adherence program; if after the agreed-upon time cutoff the additional data shows expected outcomes, the product is funded

- **REBATE FOR NON-RESPONDERS**
  - Agreement that enables a rebate for costs for **patients that were non-responders**

- **GUARANTEED ADHERENCE FOR DIFFICULT PATIENTS**
  - Agreement that enables a rebate for costs every time a patient misses an agreed upon number of doses

Please select OPTION A or OPTION B.

**In a Pay-For-Performance agreement, when should a manufacturer issue an agreed-upon rebate?**

(A) Patient **DOES NOT** reach an agreed upon clinical outcome

(B) Patient **DOES** reach an agreed upon clinical outcome
Traditionally, Pay-For-Performance agreements trigger a rebate when a pre-agreed outcome is not met.

**PAY-FOR-PERFORMANCE TRADITIONAL METRICS**

**PAY-FOR-PERFORMANCE AGREEMENTS**

**PAY FOR PERFORMANCE**
- Manufacturer offers payer authorities a rebate for patients meeting pre-agreed clinical outcomes

**PAY FOR NON-PERFORMANCE**
- Manufacturer issues rebates when patient do not achieve agreed-upon clinical outcomes

However, with adherence-based contracts incentivizing positive adherence rather than non-adherence may lead to better treatment outcomes.

**PAY-FOR-PERFORMANCE TRADITIONAL METRICS**

**PAY-FOR-PERFORMANCE AGREEMENTS**

**PAY FOR PERFORMANCE**
- Manufacturer offers payer authorities a rebate for patients meeting pre-agreed clinical outcomes

**PAY FOR NON-PERFORMANCE**
- Manufacturer issues rebates when patient do not achieve agreed-upon clinical outcomes

**IMPLICATIONS FOR ADHERENCE**
- Can align incentives between all participating stakeholders
- Incentivizes and promotes positive patient adherence, which may lead to improved patient outcomes
- Potential to demonstrate long-term cost-offsets

**IMPLICATIONS FOR ADHERENCE**
- Can mitigate concerns around potential budget; however, product value may not be maximized
- Incentivizes and promotes patient non-adherence, which is related to poor outcomes
Rebates for positive adherence have the potential to align incentives between patients, physicians, manufacturers and payers.

**REBATES FOR POSITIVE ADHERENCE**

**STAKEHOLDER INCENTIVES**

Greater engagement in the management of their disease & improved clinical outcomes and QoL, associated with better adherence.

Information on treatment outcomes is readily available and can aid treatment selection and management of the disease.

In commoditized spaces, opportunity to create differentiation from the competition; incentivizing positive adherence could also increase product utilization and outcomes.

Promoting adherence can lead to better institutional health outcomes, potential cost-offsets.

Coverage with evidence development provides manufacturers the opportunity to generate local real world evidence while waiting for formalized funding.

**COVERAGE WITH EVIDENCE DEVELOPMENT**

**OVERVIEW**

**CONTRACT OVERVIEW**

- **CONDITIONAL FUNDING**
  - Conditional funding for 2 years, with price guarantee
- **DATA COLLECTION**
  - Continuous data collection and analysis
- **FINAL READOUT**
  - Final data review 2 years after initiations

If primary endpoint is not met, rebates are triggered.

**OUTCOMES MET**

**OUTCOMES NOT MET**

**BENEFITS**

- **MFG**: opportunity to collate local RWE and physician experience that may serve to differentiate the product from local competitors
- **PAYERS**: reassurance product is efficacious in the local setting
- **PHYSICIANS**: better disease management, given RWE and adherence data

**POTENTIAL RISKS**

- **MFG**: RWE may not generate data that enhances the value of the product, risking loss of funding and / or larger rebates
Opportunity for implementation of adherence-based contracts will vary across different payer archetypes in LatAm.

**PAYER ARCHETYPES**

- **SPECIALTY HOSPITALS**
- Some private payers and specialty hospitals have an integrated provider network and have more flexibility to engage in alternative contracts

- **PRIVATE SECTOR**

- **PUBLIC EARLY ACCESS**

- **LARGE PUBLIC PAYERS**

  
  Procurement through tenders and / or wholesalers can at times be a hurdle for implementation of contracts, but pockets of opportunity exist with select payers

Specialty hospitals generally have a slightly higher WTP and better infrastructure vs. largest public institutions, therefore being an attractive pocket for ABC.

**MARKET SEGMENTS**

**SPECIALTY HOSPITALS**

- **UMAEs**
  - Direct negotiations (i.e., may by-pass the tender)
  - Opportunity for funding even if not in “Cuadro Basico”

- **IPS**
  - Direct negotiations or through wholesalers, often in collaboration with EPS
  - Single institution with self network
  - Serve as service providers for EPS

- **SPECIALTY HOSPITALS**
  - Opportunity for direct negotiation
  - Single institution with self network

**OPPORTUNITIES**

- Small number of patients may limit revenue potential
- General procurement through tenders

**ISSUES & RISKS**

- Need to align incentives between IPS, EPS and wholesalers

- Small number of patients, may limit uptake
- May call for tenders in highly competitive Tas (e.g., RA., AS, MS)
LatAm markets have a flourishing private sector that could be an early adopter of electronic monitoring.

**PRIVATE SECTOR**

**MARKET SEGMENTS**

<table>
<thead>
<tr>
<th>OPPORTUNITIES</th>
<th>ISSUES &amp; RISKS</th>
</tr>
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<tbody>
<tr>
<td>HMOs</td>
<td></td>
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<tr>
<td>Direct negotiations</td>
<td>Funding not mandated if not include in the Rol from ANS, need to gain access through individual providers</td>
</tr>
<tr>
<td>Integrated provider network</td>
<td></td>
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<tr>
<td>Patient volumes (9.25% of BRA market; ~ 19.2 million)</td>
<td></td>
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</table>

| UNIMED |               |
| Direct negotiations | Funding not mandated if not include in the Rol from ANS, need to gain access through individual providers |
| Integrated provider network | |
| Patient volumes (9.00% of BRA market; ~ 18.6 million) | |

| PREPAGAS |               |
| Opportunity for direct negotiation | Funding is not centrally regulated, and may vary between depending on inclusion in individual vademecums |
| Some PREPAGAS have an integrated provider network | |

| PRIVATE |               |
| Opportunity for direct negotiation | Small patient volume (5% of MEX population) |
| Some may have an integrated provider network | |
| Physicians often have a public and private practice, therefore can be advocated in the public payers | |

Smaller public institutions may serve as early access routes given they provide more flexibility that larger public institutions.

**EARLY PUBLIC SEGMENTS**

**MARKET SEGMENTS**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>STATE FUNDING</td>
<td>Tender-based procurement</td>
</tr>
<tr>
<td>Decisions may indirectly influence private and public providers</td>
<td></td>
</tr>
<tr>
<td>Funding for non-COMITEC indications</td>
<td></td>
</tr>
<tr>
<td>Patient volumes (28% of BRA market; ~ 75.5 million)</td>
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</tbody>
</table>

| OPDs (e.g., SEDENA, SEMAR) |               |
| Integrated provider network | May opt for joining centralized negotiations (mesa negociadora) and tender |
| Opportunity exists to opt out of tender | |
| Higher WTP vs. other public institutions | |
| Prior experience with Pay-for-Performance | |

| OS-PROVINCIAL |               |
| Opportunity for direct negotiation | Decentralized system of OS-P. would require a strong field team to engage with all ove |
| Integrated provider network | |
Public and social security sector are the largest in volume, but traditionally cost-driven with limited examples of implementation of alternative contracts.

### MARKET SEGMENTS

<table>
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<tr>
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<th>POCKETS OF OPPORTUNITY</th>
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<tbody>
<tr>
<td><strong>OPPORTUNITIES</strong></td>
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</tr>
<tr>
<td>SUS BRA</td>
<td>• Highest patient volume opportunity in BRA</td>
</tr>
<tr>
<td>• Price-driven single award tender procurement</td>
<td></td>
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<tr>
<td>• Limited experience with outcomes-based based agreements</td>
<td></td>
</tr>
<tr>
<td>IMSS, ISSSTE, SP MEX</td>
<td>• Highest patient volume opportunity in MEX</td>
</tr>
<tr>
<td>• Competitive single-award tender system</td>
<td></td>
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<tr>
<td>• Price erosion through reverse action tenders</td>
<td></td>
</tr>
<tr>
<td>• Prescription limited to the tender brand</td>
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<tr>
<td>OS: NACIONALES ARG</td>
<td>• Provides coverage to the employed (majority of the population)</td>
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<tr>
<td>• High cost drugs founded through SUR</td>
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</tr>
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<td>• Funding is not centrally regulated, and may vary between depending on inclusion in individual vademecums</td>
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<td>EPS COL</td>
<td>• Opportunity for direct negotiation with IPS and wholesalers</td>
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For a copy of this presentation, please contact us:

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