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All about data – leveraging the Patient Support Program (PSP)

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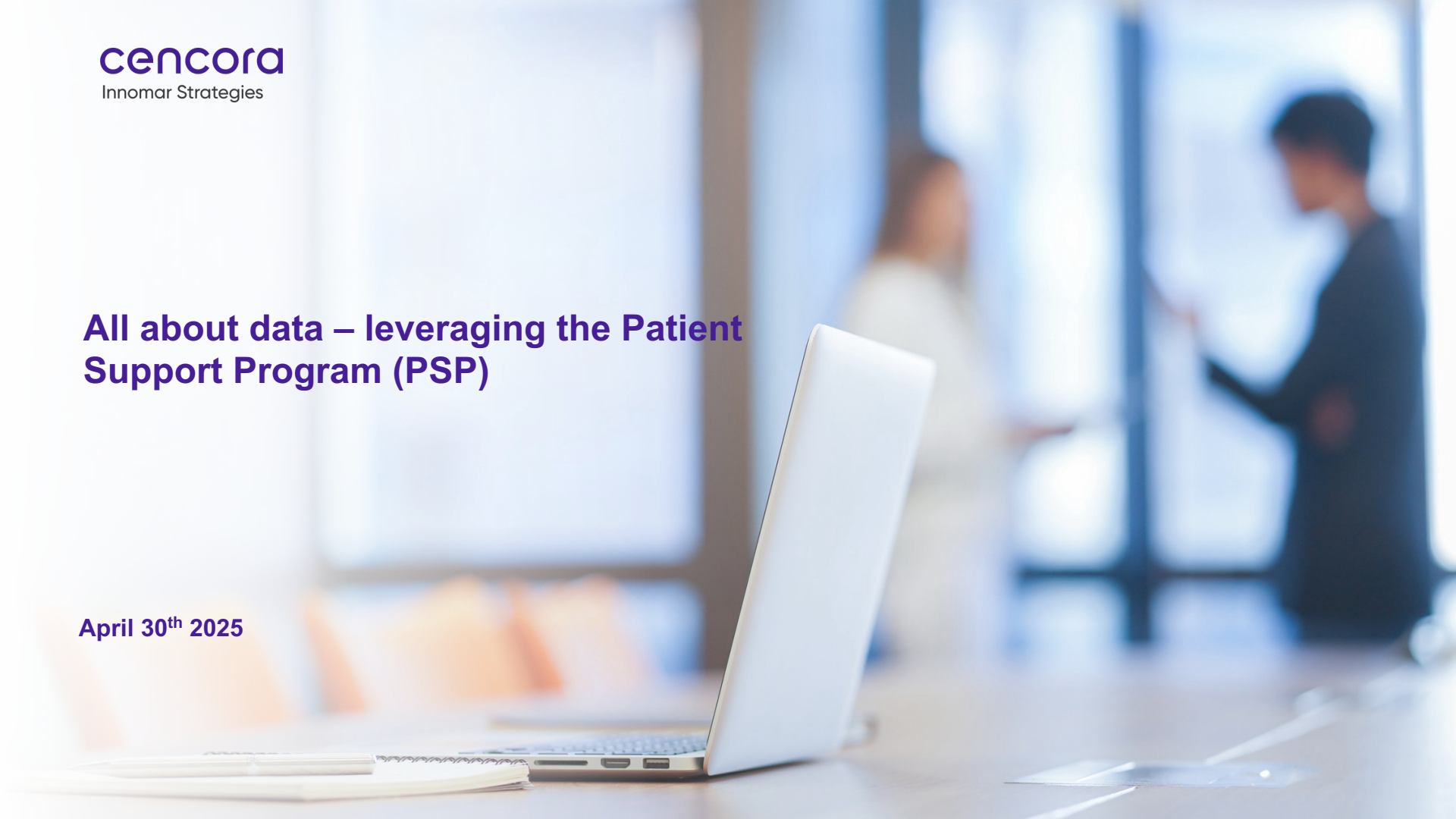

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Why a Patient Support Program in rare?

Enhance patients' experience on therapy

Patient access

- Advocate and assist patients who are too sick to do it for themselves
- Limit anxiety and educate patients
- SAP and Clinical Trial conversion
- Assist patients through the complex Special Authorization (SA) process
- Minimize drop offs

Fast initiation of treatment

Treatment access

- Secure funding for enrolled patients
- Lobbying/ appeals
- Expertise in working with HCPs and insurers for SA completion/approvals
- Work with advocacy groups

Ensure patient can access therapy

Co-pay, bridging and compassionate use

- Co-pay integrated into PSP
- Financial assessment done at time of reimbursement completion
- Integrated with Innomar Specialty pharmacy
- Managed distribution and pharmacy

Rare and orphan disease depth & breadth | payer relationships

Data via the patient journey

Patient support programs

- Consent management
- Various mediums to communicate with patients (phone, portal etc.)
- PSP validated CRM
- Adverse Events reporting
- Side effect management

Data sources

- Patient registries
- Pharmacy
- Wholesale
- Hospitals
- EMR
- Health case management
- Chart Audits

Evidence generation

- Burden of illness
- Drug utilization and treatment patterns
- Meta-analyses
- Budget impact and cost-effectiveness analyses
- Retrospective and prospective studies
- Publications

Leverage insights across the therapeutic lifecycle → Data that is payer driven for PLAs, OBAs, renewal criteria

PSP as platform for RWE and data insights

Retrospective	Retrospective + Prospective	Prospective
Legacy • Persistence • Optimal dosing • Prescription practices and treatment pattern • Adherence (if pharmacy data available) • Mortality	**Additive or Complimentary** • Clinical outcomes/ PRO specified in reimbursement criteria • Detailed treatment pattern • Switching of treatment routes • Progression of treatment location	**Future** • Demonstrate more robustly clinical value • Demonstrate economic value • Real-time data collection to minimize recall bias • Build on evidence lead against upcoming competitors

PSP RWE: opportunities and challenges

Challenges

Not comparative

Confounders

Potential selection bias

Lack of parallel control cohort

Not a substitute for RCTs

Often relies on patient recall

Often not enough data to utilize as stand alone

Opportunities

Truly Canadian evidence

Long duration of engagement with patients

Generalizability, potentially internationally

Characterize practice patterns, unmet medical needs and burden of illness

Prospective/retrospective analyses

Support HTA submissions

Guide pricing and listing negotiations

High incremental value

Case studies

Case example 1: RWE to support Health Canada priority review request for a life-threatening rare disease

Situation

- IV formulation of product approved by Health Canada and currently marketed
- Client seeking Priority Review for oral formulation
- Value proposition
  - Introduction of an oral formulation will eliminate the inherent risk of exposure to AEs associated with IV route of administration and will further improve the overall safety profile of product

Approach

- Canadian patient experience data on IV formulation collected through PSP
  - Reports of AEs to manufacturer's drug safety department
- RWE generation
  - Analysis focused on Infusion-associated AEs

Results

- Positive outcome - HC granted priority review for oral formulation of the product based on RWE submitted

Case example 2: Linkage between PSP and patient registry

Situation

- Augmentation therapy with intravenous plasma-derived alpha-1 antitrypsin protein (AUG) is available to some Canadians with lung disease due to AATD
- The management of flares is associated with a substantial financial healthcare burden
- AlphaNet Canada (ANC) follows individuals with AATD and collects HRQoL data

Approach

- The data set included AATD patients enrolled in Innomar's PSP (between June 2008 and July 2019) prescribed AUG, some of whom were able to receive AUG (AUG group) while others were not (Control group)
- Demographic data from Innomar were combined with exacerbation data, SF-36 and Saint George's Respiratory Questionnaire (SGRQ) scores from ANC

Results

- This pilot study suggested the group receiving AUG compared to the control group had improvements in 1) exacerbation number and severity, 2) in SGRQ and SF-36; 3) reduction in health resource utilization
- AUG may slow QoL decline and reduce the number of severe exacerbations in those with AATD compared to those not receiving AUG