AI in Drug Safety Operations - The Future is Here!

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An AI-first company leveraging technology for better health outcomes

Leveraging Technology for Patient Safety

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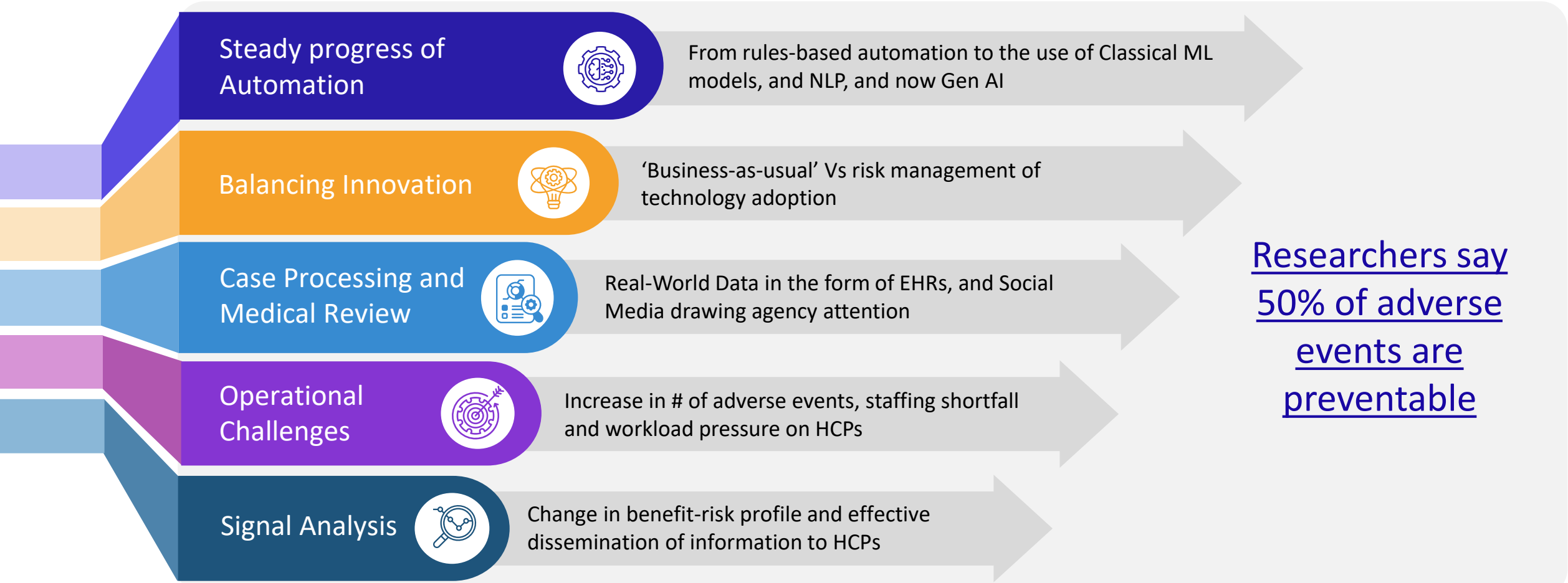

Accelerate technology adoption to improve health outcomes

AI Adoption – Navigating through the Hype

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Compliance, Security and Privacy:

- Using 'Data' as evidence
- Build stakeholder trust
- AI/ML Validation strategy

Accuracy & Explainability:

- Interpretability
- Mitigate ‘Bias’ and ‘Hallucination’
- Change Management

Data Quality:

- Automation of data standardization
- **4Vs** - Veracity, Variety, Velocity and Volume
- Data quality monitoring

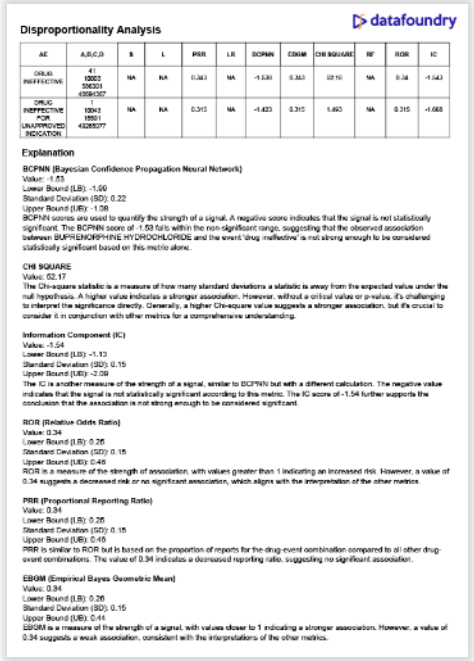
Cost-Benefit Analysis:

- Choosing the right automation technique – PoC to Production
- Operationalizing and Scaling

Domain-focused Data Science is the Game Changer

Gen AI Example – The Future is Here!

- Gen AI will transform regular operations such as case intake, processing, narrative and report generation
- Human-in-the-loop will be required to confirm/validate medical review and analysis.



Disproportionality Analysis

AE	A,B,C,D	S	L	PRR	LR	BCPNN	EBGM	CHI SQUARE	RF	ROR	IC
DRUG INEFFECTIVE	41 19003 506301 4306307	NA	NA	0.343	NA	-1.539	0.343	92.16	NA	0.34	-1.543
DRUG INEFFECTIVE FOR UNAPPROVED INDICATION	1043 18501 4326577	NA	NA	0.315	NA	-1.423	0.315	1.493	NA	0.315	-1.668

Explanation

BCPNN (Bayesian Confidence Propagation Neural Network)
Value: -1.53
Lower Bound (LB): -1.99
Standard Deviation (SD): 0.22
Upper Bound (UB): -1.08
BCPNN scores are used to quantify the strength of a signal. A negative score indicates that the signal is not statistically significant. The BCPNN score of -1.53 falls within the non-significant range, suggesting that the observed association between BUPRENORPHINE HYDROCHLORIDE and the event 'drug ineffective' is not strong enough to be considered statistically significant based on this metric alone.

CHI SQUARE
Value: 92.17
The Chi-square statistic is a measure of how many standard deviations a statistic is away from the expected value under the null hypothesis. A higher value indicates a stronger association. However, without a critical value or p-value, it's challenging to interpret the significance directly. Generally, a higher Chi-square value suggests a stronger association, but it's crucial to consider it in conjunction with other metrics for a comprehensive understanding.

Information Component (IC)
Value: -1.54
Lower Bound (LB): -1.13
Standard Deviation (SD): 0.15
Upper Bound (UB): -2.09
The IC is another measure of the strength of a signal, similar to BCPNN but with a different calculation. The negative value indicates that the signal is not statistically significant according to this metric. The IC score of -1.54 further supports the conclusion that the association is not strong enough to be considered significant.

ROR (Relative Odds Ratio)
Value: 0.34
Lower Bound (LB): 0.26
Standard Deviation (SD): 0.15
Upper Bound (UB): 0.46
ROR is a measure of the strength of association, with values greater than 1 indicating an increased risk. However, a value of 0.34 suggests a decreased risk or no significant association, which aligns with the interpretation of the other metrics.

PRR (Proportional Reporting Ratio)
Value: 0.34
Lower Bound (LB): 0.26
Standard Deviation (SD): 0.15
Upper Bound (UB): 0.46
PRR is similar to ROR but is based on the proportion of reports for the drug-event combination compared to all other drug-event combinations. The value of 0.34 indicates a decreased reporting ratio, suggesting no significant association.

EBGM (Empirical Bayes Geometric Mean)
Value: 0.34
Lower Bound (LB): 0.26
Standard Deviation (SD): 0.15
Upper Bound (UB): 0.44
EBGM is a measure of the strength of a signal, with values closer to 1 indicating a stronger association. However, a value of 0.34 suggests a weak association, consistent with the interpretations of the other metrics.

An example of LLM generated Signal Detection

Safety Operations – Prepare to be transformed

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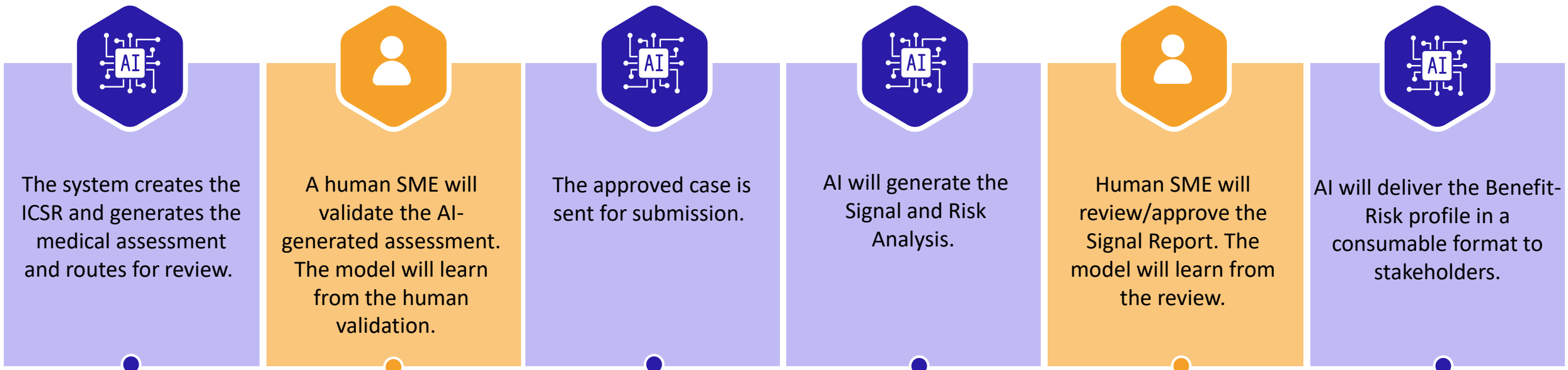
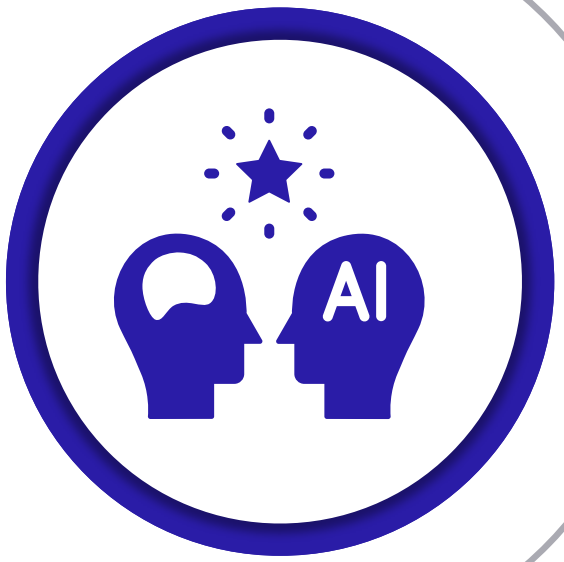
The case data is fed into a multi-source and multi-modal system, processed by a Gen AI-driven workflow



AI-assisted Use Cases – Disrupting Traditional Processes



EHRs could potentially become the **single source** of reporting globally

Goal would be to ensure data quality when reporting for the first time

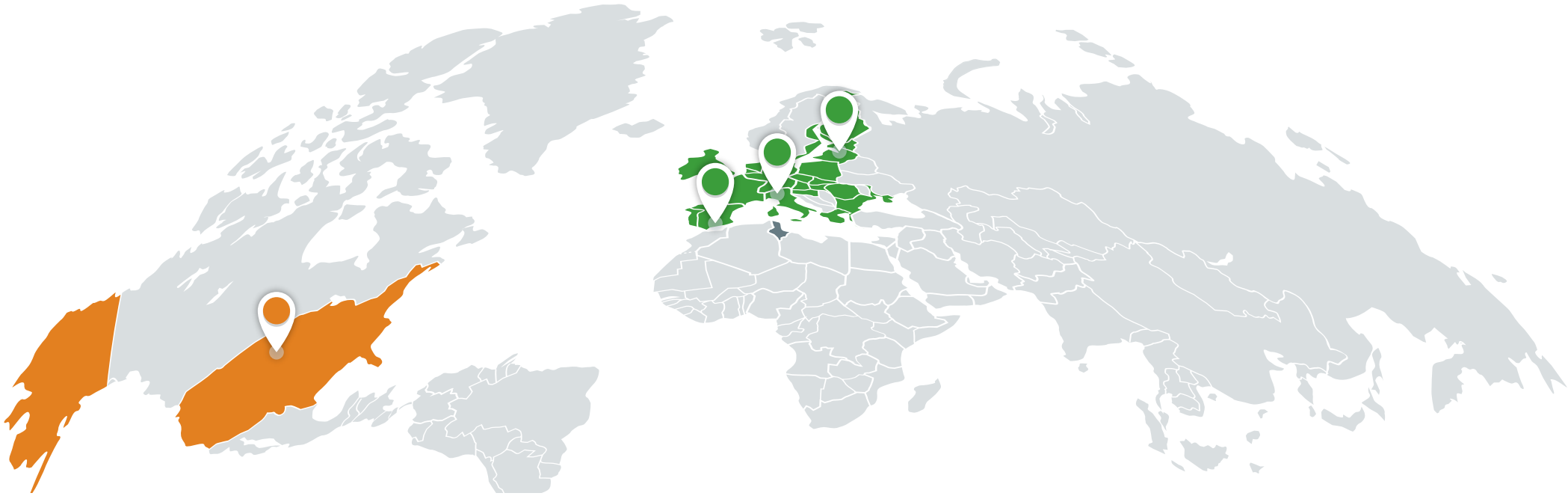
Apps for safety reporting can facilitate:

- AE reporting by HCPs and Patients
- **Voice to Text to E2B R3**
- Export E2B XML into the Safety system
- Product complaints tracking
- Access label information in digital format
- Verify the drug source – Spuriousness check
- Companies receive drug purchase and usage data
- Chat with AI agent

A combination of human + AI agents can do the follow-ups

Medical reviewers can focus on complex cases as the case processing time is reduced by 80%

Regulatory Authority Initiatives



US FDA - CBER's Biologics Effectiveness and Safety (BEST) System

*Develops innovative methods to utilize **electronic health records (EHR)** effectively and establish **automated adverse events reporting, utilizing natural language processing and AI***

WHO Vigibase

Uses AI algorithms to analyze large volumes of safety reports to detect emerging patterns

EMA Eudravigilance

Uses AI algorithms to identify potential signals from data reported by patients and HCPs

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

The Spanish RA has started using AI algorithms to aid swift detection of adverse events.

When Artificial General Intelligence(AGI) becomes a reality…

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Comprehensive
Data Convergence

SME/Expert Analyses

Near Real-time Updates

Input Dataset

User Experience

Analytics and Prediction dashboards

AI + Human authored Reports

Unified Regulatory Framework

AI = Actionable Intelligence for HCPs and patients

Thank You

Datafoundry is at **Booth #120**

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