COLOMBIA POTENCIA DE LA VIDA

Salud

X ENCUENTRO NACIONAL DE FARMACOVIGILANCIA

NUEVAS TECNOLOGÍAS EN FARMACOVIGILANCIA

RETOS Y AVANCES PARA SU IMPLEMENTACIÓN EN COLOMBIA

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Farmacovigilancia en la era digital

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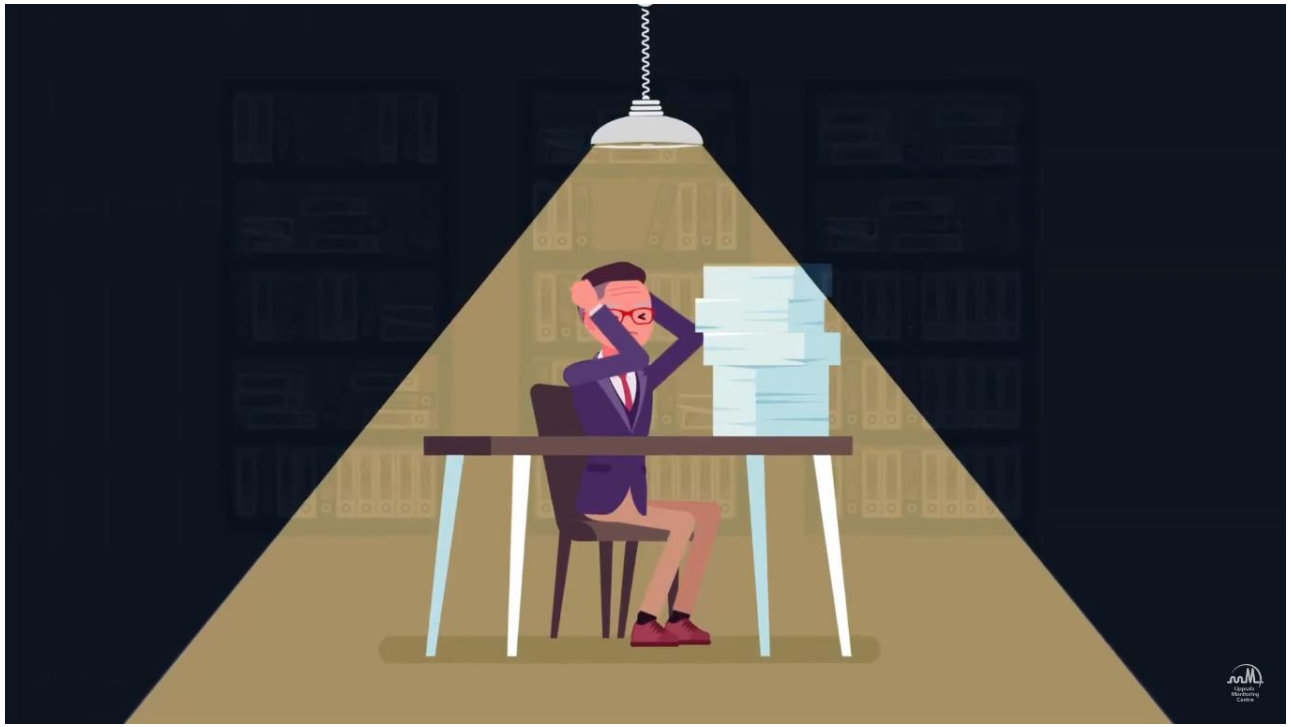
Conflicto de interés

Ninguno

Prologo



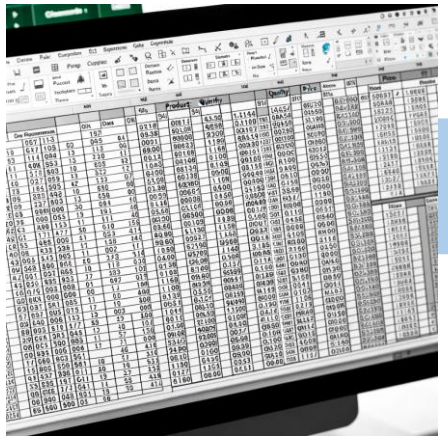
Fuente: Uppsala Monitoring Centre

Fuente: OpenAI. (6 de octubre de 2023). Imagen generada por ChatGPT para ilustrar conceptos del Dato.

Fuente: OpenAI. (6 de octubre de 2023). Imagen generada por ChatGPT para ilustrar conceptos del Dato.

Tipo de datos

Datos Estructurados



Información tabulada:
Medicamentos prescritos
Medicamentos dispensados
Resultados de exámenes paraclínicos

Datos No Estructurados

Información sin formato rígido:
Texto libre (notas médicas)
Imágenes diagnósticas
Audio/Video
Correos electrónicos

Fuente: OpenAI. (6 de octubre de 2023). Imagen generada por ChatGPT para ilustrar conceptos del Dato.

Etapas en el análisis de datos

Fuente: Imagen de origen desconocido. Consultado 06 de octubre de 2023.

Entrando en la era digital

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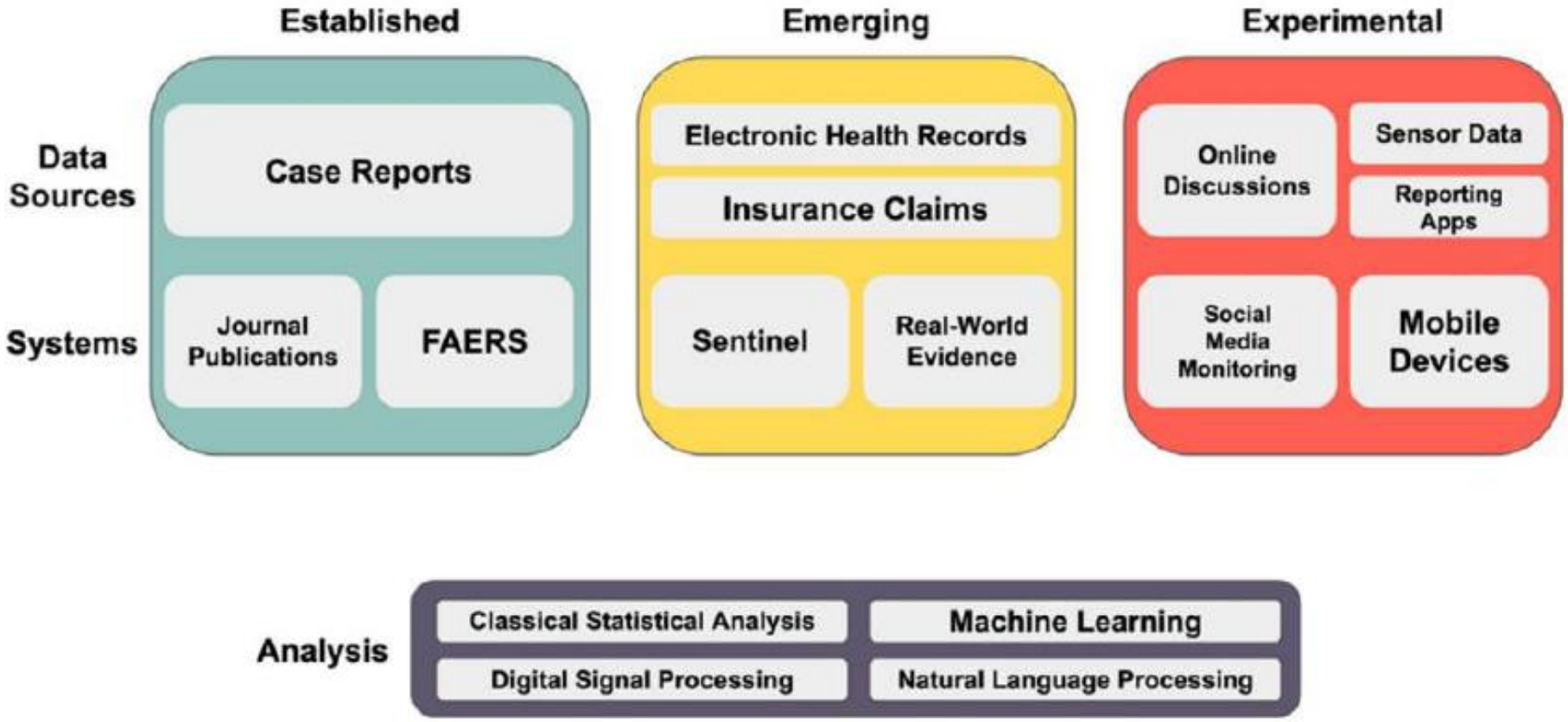
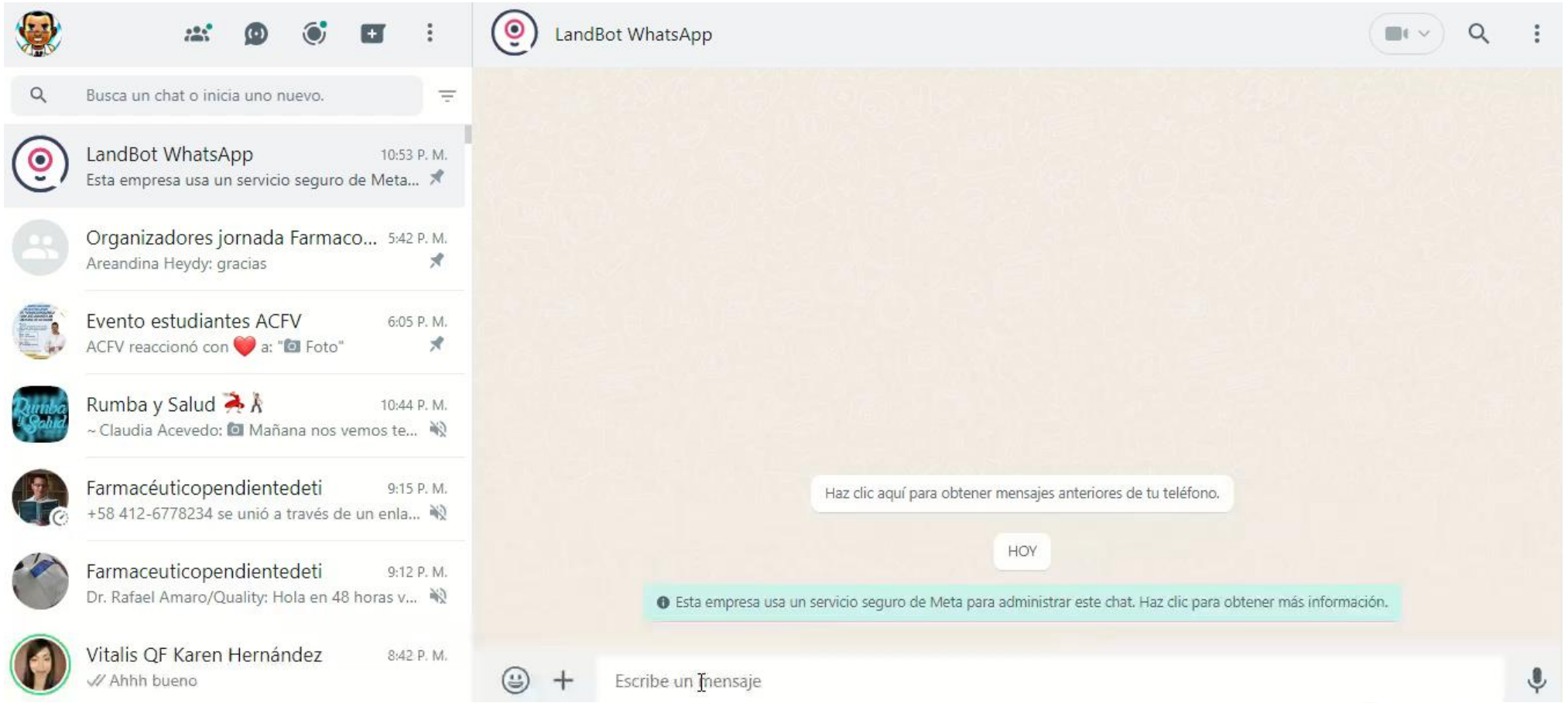
Etapas de desarrollo de la Farmacovigilancia



Fuente: Lavertu, A., Vora, B., Giacomini, K. M., Altman, R., & Rensi, S. (2021). A New Era in Pharmacovigilance: Toward Real-World Data and Digital Monitoring. Clinical pharmacology and therapeutics, 109(5), 1197–1202. https://doi.org/10.1002/cpt.2172

Chatbots en educación, adherencia, reportes, etc.



Fuente: Creación propia.

Análisis de Desproporcionalidad: OpenVigil FDA

OpenVigil - open tools for data-mining and analysis of pharmacovigilance data

Open Vigil
a pharmacovigilance data analysis tool

OpenVigil Search

Drug: Drug | acetaminophen | Role of drug: Do not filter | +

Adverse event: LLT | administration site rash | +

Advanced search
Show advanced search

Data presentation and statistics
Evaluation method: Raw_data | Frequency | Frequentist_methods
Counting records according to: Case (entire cases)

Output items
Show output items

Show query

	Drug(s) of interest	All other drugs	∑
Adverse event(s) of interest	1	61	62
All other adverse events	382148	11057546	11439694
∑	382149	11057607	11439756

Rate (DE/D): 0.0%

Chi-Squared with Yates' correction: 0.163
Interpretation: Do the observed frequencies differ from expected frequencies? The greater the chi-squared value, the greater the differences. Chi square va

Measurements of disproportionality (observed-expected ratios like RRR, PRR, ROR)
Interpretation: Generally, the higher the value, the more likely an association between drug(s) and adverse event(s) has been found. Lower bounds of confi statistical significance.

Relative Reporting Ratio (RRR) and 95% confidence interval (lower bound; upper bound): 0.483 (0.067 ; 3.482)

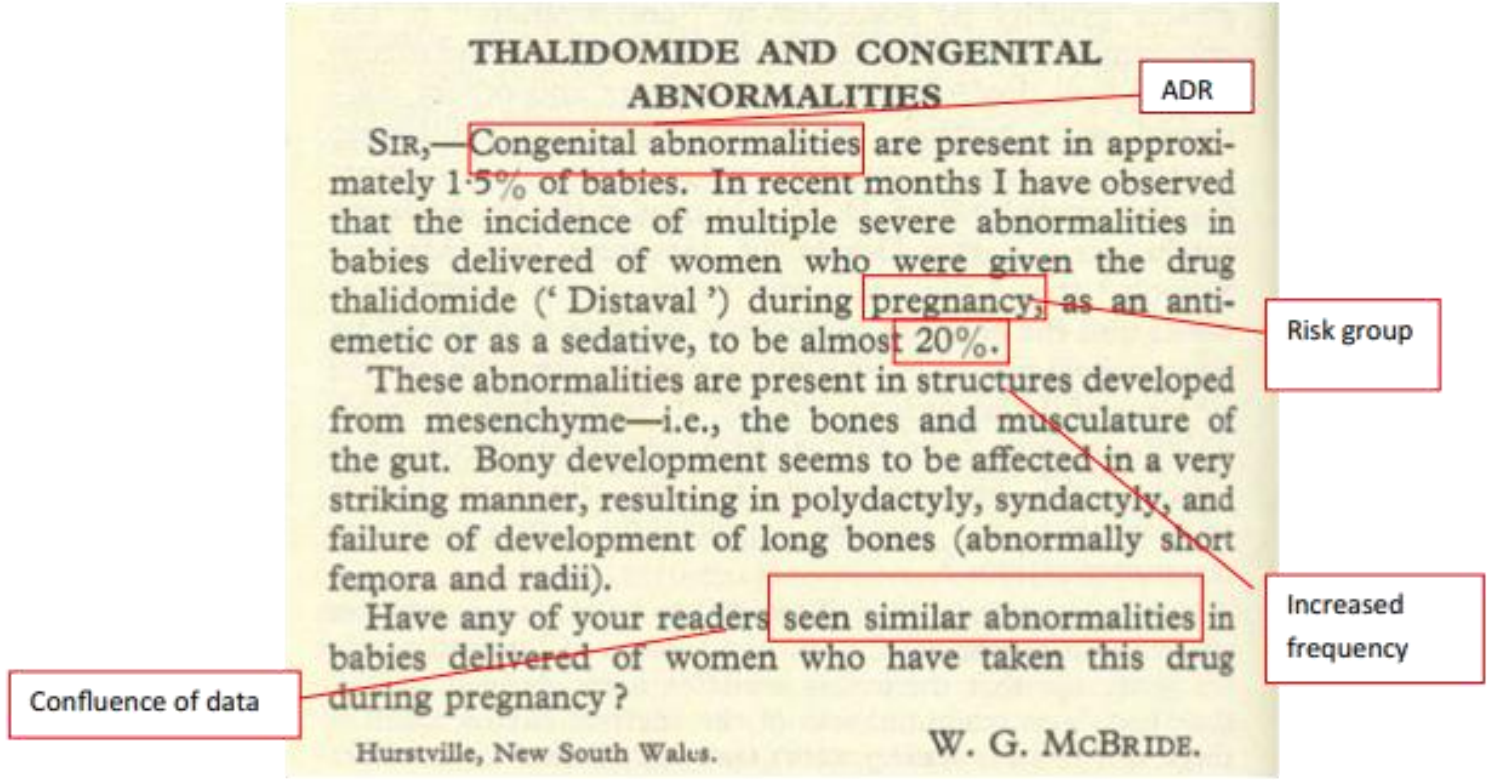
Proportional Reporting Ratio (PRR) and 95% confidence interval (lower bound; upper bound): 0.474 (0.066 ; 3.422)

Reporting Odds Ratio (ROR) and 95% confidence interval (lower bound; upper bound): 0.474 (0.066 ; 3.422)

According to the criteria of Evans 2001 (n > 2, chisq > 4, PRR > 2) this combination of drug(s) and adverse event(s) is considered: probably not related

Fuente: OpenVigil. OpenVigil - open tools for data-mining and analysis of pharmacovigilance data. Disponible en: https://openvigil.sourceforge.net/. Consultado el 6 de octubre de 2023.

Uso de *Natural Language Processing* en el análisis de textos



THALIDOMIDE AND CONGENITAL ABNORMALITIES

SIR,—Congenital abnormalities are present in approximately 1·5% of babies. In recent months I have observed that the incidence of multiple severe abnormalities in babies delivered of women who were given the drug thalidomide (' Distaval ') during pregnancy, as an antiemetic or as a sedative, to be almost 20%.

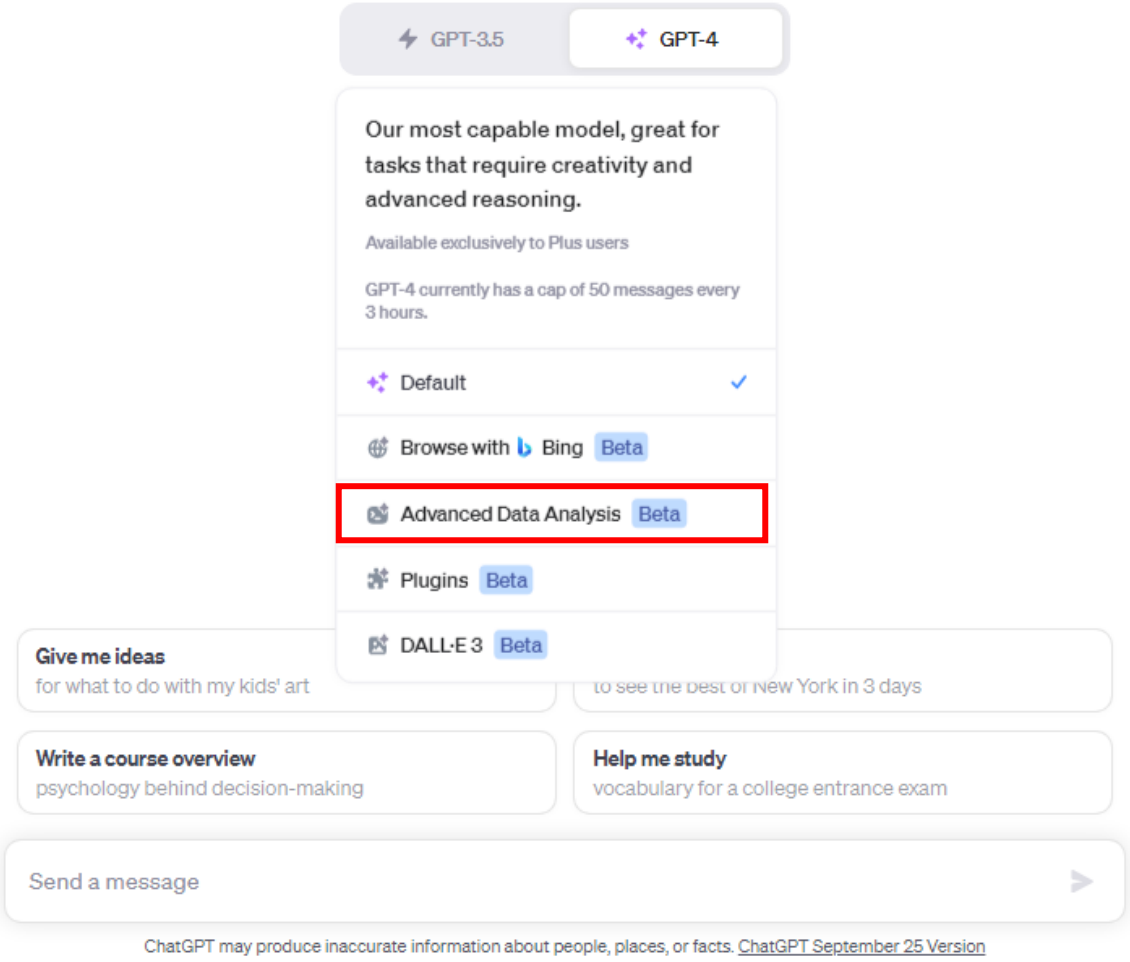
These abnormalities are present in structures developed from mesenchyme—i.e., the bones and musculature of the gut. Bony development seems to be affected in a very striking manner, resulting in polydactyly, syndactyly, and failure of development of long bones (abnormally short femora and radii).

Have any of your readers seen similar abnormalities in babies delivered of women who have taken this drug during pregnancy?

Hurstville, New South Wales. W. G. MCBRIDE.

Fuente: Fornasier, G; et al. An historical overview over Pharmacovigilance. 2018

Chat GPT-4: *Advanced Data Analysis*



Drug Safety (2023) 46:711–713
https://doi.org/10.1007/s40264-023-01315-2

EDITORIAL

Future of ChatGPT in Pharmacovigilance

Hanyin Wang[1] · Yanyi Jenny Ding[1] · Yuan Luo[1]

Accepted: 27 April 2023 / Published online: 12 June 2023

7th ISoP Seminar – Intelligent Automation in Pharmacovigilance

4-5 Dec 2023 | Cambridge, MA, USA

SAVE THE DATE. 7th ISoP Intelligent Automation in Pharmacovigilance Seminar

Fuente: International Society of Pharmacovigilance. Disponible en: https://isoponline.org/training/seminar/isop-seminar-2023/. Consultado el 6 de octubre de 2023.

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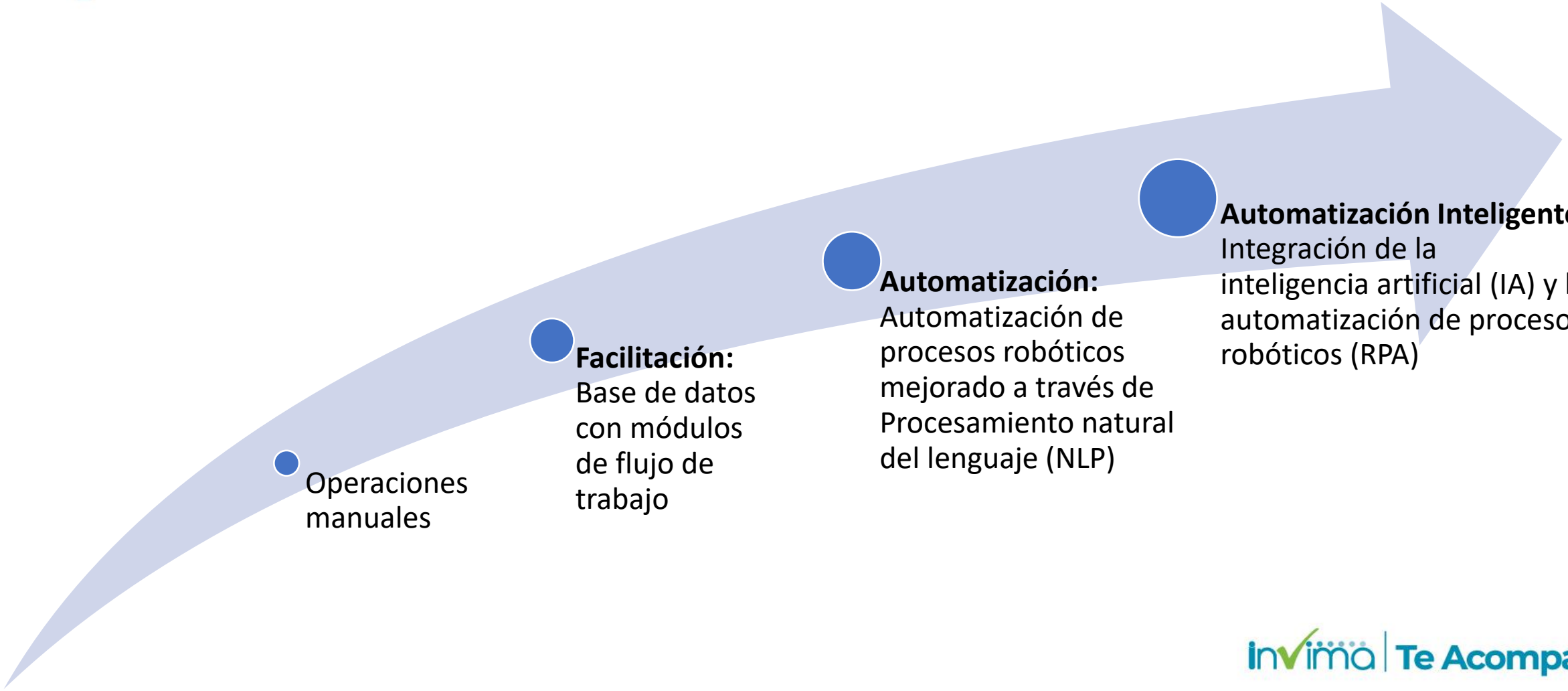
Trayectoria de la automatización en Farmacovigilancia



Validación del sistema de Automatización Inteligente

Drug Safety (2021) 44:261–272
https://doi.org/10.1007/s40264-020-01030-2

LEADING ARTICLE

Check for updates

Validating Intelligent Automation Systems in Pharmacovigilance: Insights from Good Manufacturing Practices

Kristof Huysentruyt[1] · Oeystein Kjoersvik[2] · Pawel Dobracki[3] · Elizabeth Savage[4] · Ellen Mishalov[5] · Mark Cherry[6] · Eileen Leonard[7] · Robert Taylor[8] · Bhavin Patel[9] · Danielle Abatemarco[10]

Accepted: 1 December 2020 / Published online: 1 February 2021

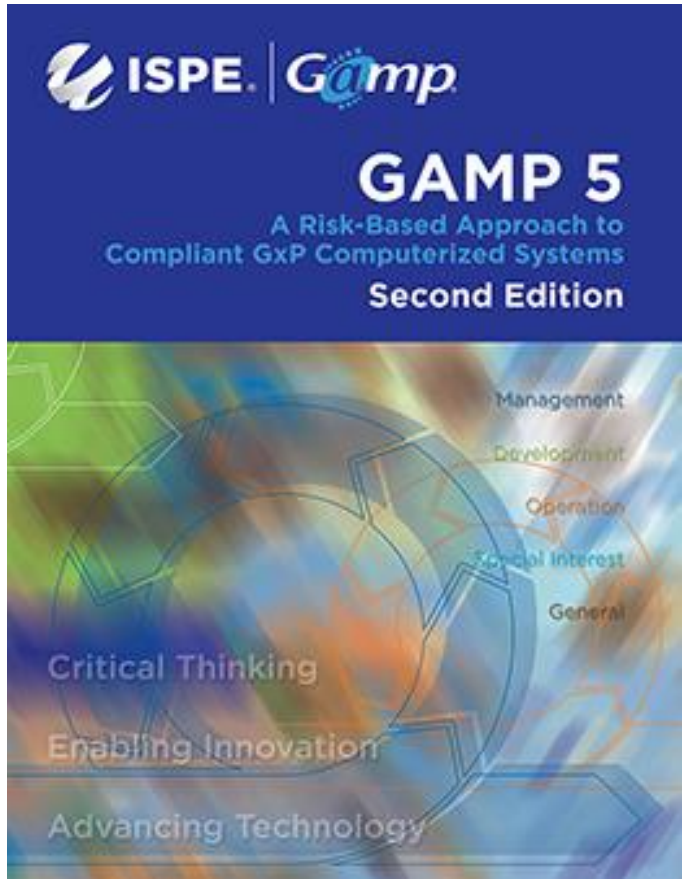


Fig. 3 Proposed ISPE GAMP® 5 methodology for validating artificial intelligence (AI)-based static systems in pharmacovigilance

Fuente: Huysentruyt, K., et al (2021). Validating Intelligent Automation Systems in Pharmacovigilance: Insights from Good Manufacturing Practices. Drug safety, 44(3), 261–272.

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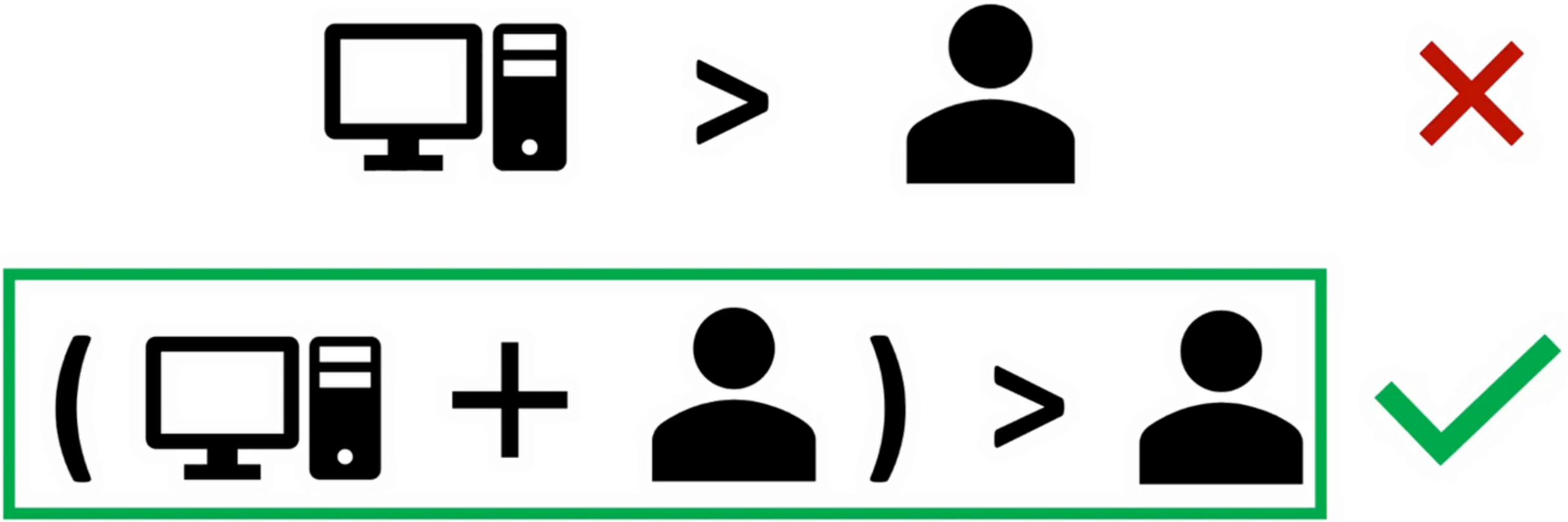
Reflexión final: “Teorema fundamental”



Fuente: Friedman CP. A “fundamental theorem” of biomedical informatics. J Am Med Inform Assoc 2009;16:169–70

GRACIAS

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