



DRUG AND THERAPEUTICS
BULLETIN OF NAVARRE,
SPAIN

Bol Inf Farmacoter Navar 2025; 32: 1-17
"Surrogate outcomes and fast-track drug approval"

Introduction

Preliminary definitions

Purpose of surrogate outcomes

General validity requirements for surrogate outcomes

What do regulatory bodies propose?

The extra requirements in the German strategy

Representative examples of surrogate outcomes: HIV infection, Hepatitis C virus infection, SARS-Cov-2 infection, High blood pressure, Dyslipidaemia, Diabetes, Osteoporosis, Alzheimer's disease, Cancer

Ataluren: the failed drug that calls for reflection

Harmful drug + fast-track access = late protection

A brief elegy to the clinical trial

Conclusions

References

<https://doi.org/10.54095/BITN20253201EN>



SALUD
Y FÁRMACOS

Boletín Fármacos: Farmacovigilancia

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- Solicitudes y Retiros del Mercado
- Solicitudes y Cambios al Etiquetado/Ficha Técnica
- Reacciones Adversas
- Interacciones
- Precauciones
- Otros Temas de Farmacovigilancia

<https://www.saludyfarmacos.org/wp-content/files/feb202501.pdf>



Drug and
Therapeutics
Bulletin

Drug and Therapeutics Bulletin

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Editorial

- Prioritising shared decision-making
Michael Wilcock, David Phizackerley

DTB select

- Promising results from NHS type 2 diabetes low calorie diet programme

DTB Commentary

- Adverse effects of antihypertensives in frail older people
Joanna Owens, Teck K Khong

DTB drug review

- AWhat role for gefapixant in chronic cough?

Republished case report

- Diagnostic dilemma: drug-induced vasculitis versus systemic vasculitis
Indira Acharya, David S Weisman, Lanaya Williams Smith, Lois Johanna Arend

<https://dtb.bmj.com/content/63/2?current-issue=y>



Newsletter

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ISDB Newsletter

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- Industry Lobbyists Work to Influence U.S. Position in Critical Global Health Negotiations
- PILs: all harms and no benefits
- Patients deserve better information on new drugs
- Phasing out patient leaflets in paper form: eco-responsible or irresponsible?
- Revision of European pharmaceutical legislation: a disappointing vote in the Parliament
- Medications that are ineffective and potentially harmful
- In the US, opioid-maker Purdue is bankrupt. Its global counterparts make millions
- Preferences for speed of access versus certainty of the survival benefit of new cancer drugs: a discrete choice experiment

https://isdbweb.org/sites/default/files/2025-01/ISDB_Janvier2025.pdf