



# Using Incrementalism and Legitimacy to Ensure Ethical Use of Digital Health Data to Provide Accelerated Access to Medicines

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## Background and Aims

Provisional marketing approval and funding schemes allow medicines to be approved or funded on the basis of earlier data, with post-market data collection—including use of digital health data—to confirm their safety, effectiveness and cost-effectiveness. Ethical and responsible use of digital health data is necessary for both initiatives. This project aimed to explore the beliefs of patients and physicians from Sydney, NSW regarding post-market data collection, including digital health data, as a component of accelerated access.

## Methods

Semi-structured interviews with 18 Australian physicians and 13 patients and patient advocates; two focus groups with patients. Participants primarily from medical specialties/disease where accelerated access is actively discussed (e.g. oncology, paediatrics and rheumatology). Transcribed verbatim and analysed thematically.

## Results

There was significant diversity in stakeholder opinions. All acknowledged potential risks and benefits of increased reliance on post-market collection and use of digital health data but disagreed on magnitude and extent and how these should be balanced in both policy formation and clinical practice. Robust data collection, coupled with swift and decisive action by regulators and funders, were seen as necessary to address risks, but not all participants were confident this could be achieved.

## Discussion

Stakeholder analysis shows a range of reasonable views on how to respond to calls for increased reliance on post-market collection and use of digital health data as part of accelerated access. Policy makers should use incrementalism and legitimacy as outlined in table 1.

**Table 1: Incrementalism and legitimacy policy approaches to accelerated access to medicines**

Approach	Definition	Implementation
<b>Incrementalism</b>	Policies result from interaction and adaptation among many actors advocating different values, representing different interests and possessing different information -> incremental changes build upon previous policies	Robust schemes underpinned by high quality digital data Only use conditional funding and reimbursement schemes in cases of serious unmet need and medicines that offer clear benefits Consider other early access mechanisms e.g. publicly-funded clinical trials
<b>Procedural Legitimacy</b>	Procedural features- not substantive decision-determine legitimacy Aim is for stakeholders to understand and accept decisions about access to medicines as legitimate Accountability for reasonableness (A4R) framework outlines 4 principles for morally legitimate decision-making in healthcare: relevance, publicity, revision and enforcement	Transparency: how are key terms (effectiveness and cost-effectiveness) defined and measured, how is digital data collected and used, what forms of data are acceptable and useful Meaningful consumer engagement

## Conclusions

Incremental policy change can maintain the protections of current systems while providing faster access to new medicines where this is needed most; a focus on fair procedures will increase legitimacy and acceptability of decisions about accelerated access to medicines. Together, these approaches can guide best use of digital health data to ensure that patients receive benefits of new medicines and potential harms are minimised.