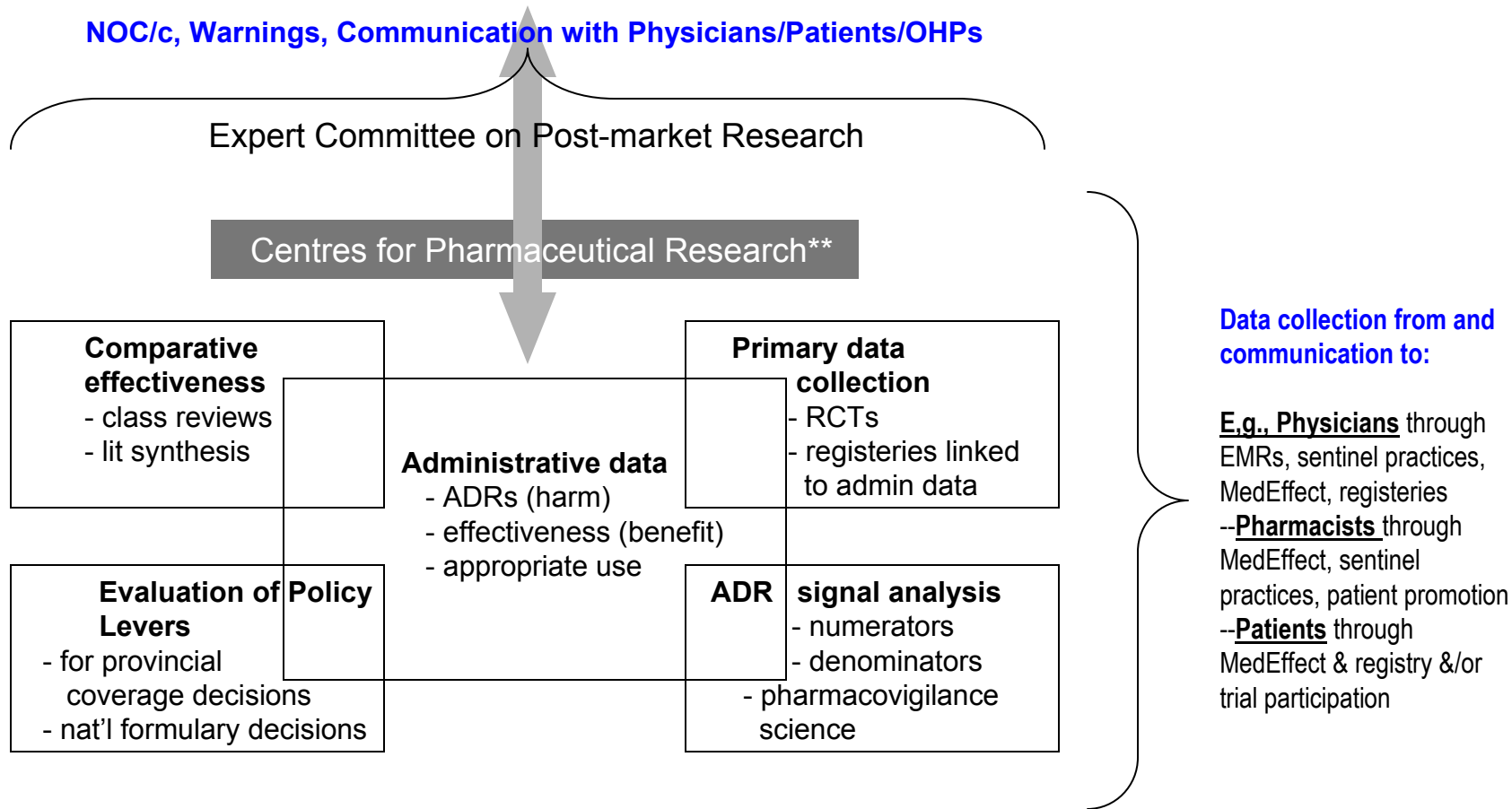


Canadian Drug Policy Development Coalition Conceptual Framework** for Post-market Research

Health Canada (TAS, MHPD) / National Pharmaceutical Strategy (Provinces)

NOC/c, Warnings, Communication with Physicians/Patients/OHPs



** This framework has been inspired by the work of Laupacis et al. CMAJ 2003; 169(11):1167-70 and others (prepared by C.Metge, Aug 2005)
Missing from the framework but included in supporting documentation: The roles of Health Research Funding Agencies like CIHR and drug sponsors

Previous Attempts

Hlynka JN. Developing a national Post-marketing Pharmaceutical Surveillance Programme (PPSP). June 1991

- The report is a blueprint for the development of a PPSP including objectives, components of PPSP required to meet the objectives, programme structure, list of participants/stakeholders that should be involved.
 - The Hlynka Report described the scope of "*post-approval surveillance as broader than the monitoring of adverse effects to licenced drugs.*"
 - Three (3) programme components
 1. Monitoring ADRs (signals from an ADR reporting system)
 2. Drug use review (appropriate use)
 3. Drug post-approval evaluation (for safety & effectiveness)
 - Research centres (public & private) to support these components

Role of Academia in Pharmacovigilance

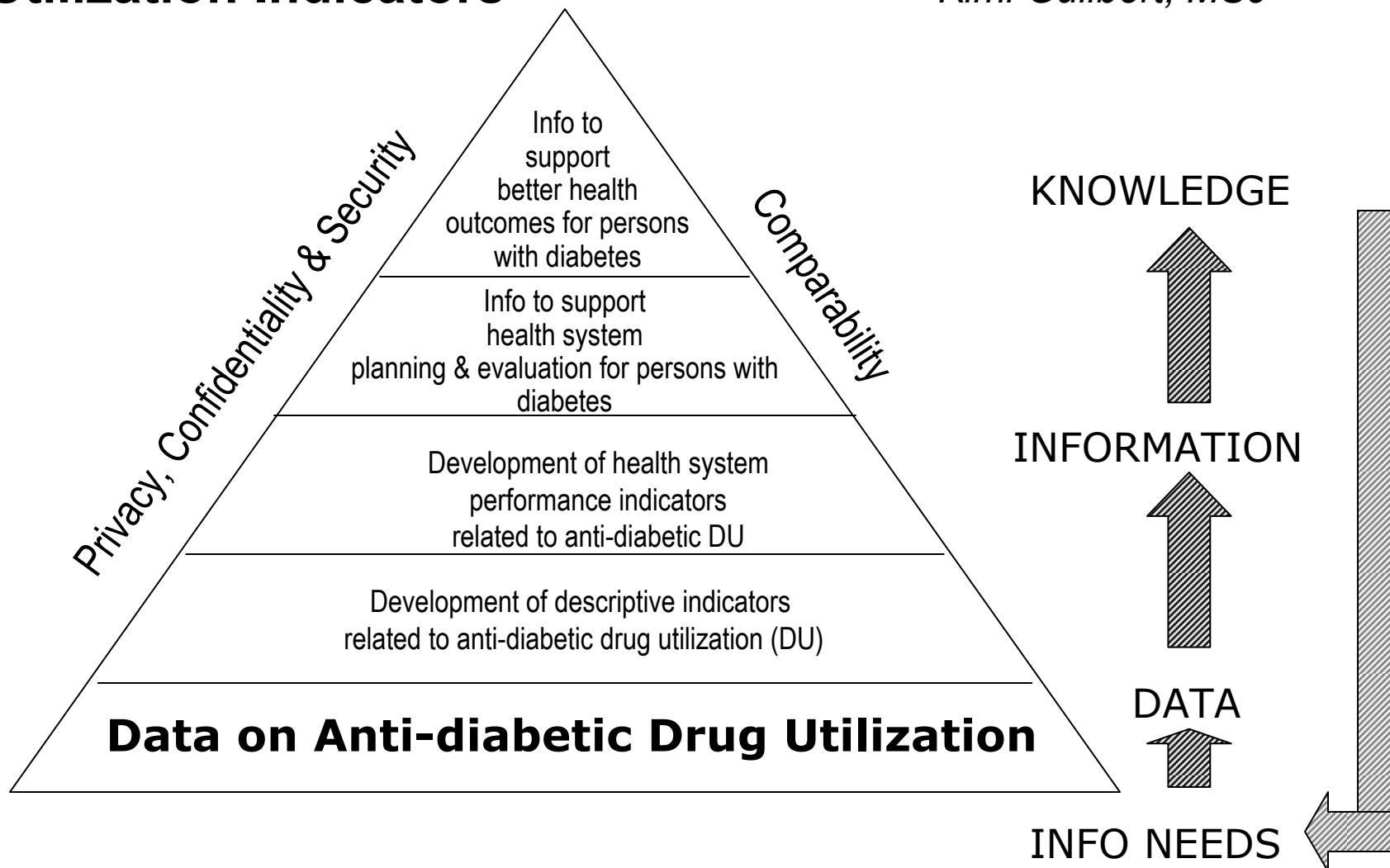
Concept of service: seeking ways to apply knowledge beyond the academy

As academics we engage not only in the enactment of knowledge but also in the application of expertise to social challenges.

*Woodrow Wilson National Fellowship Foundation
“The Responsive PhD.” Report 2005*

A Model for the Development of Anti-diabetic Drug Utilization Indicators

Kimi Guilbert, MSc



*Adapted from CIHI, 2004 (see reference in the text)

Note: The relationship between the stages is dynamic as new data must be reflected upon so that needs can be reevaluated and interventions adapted, accordingly. Comparability between provinces and across Canada is desirable and issues surrounding privacy, confidentiality and security must also guide the evolution of the stages.

Figure 3.

A Drug Product's Life Cycle

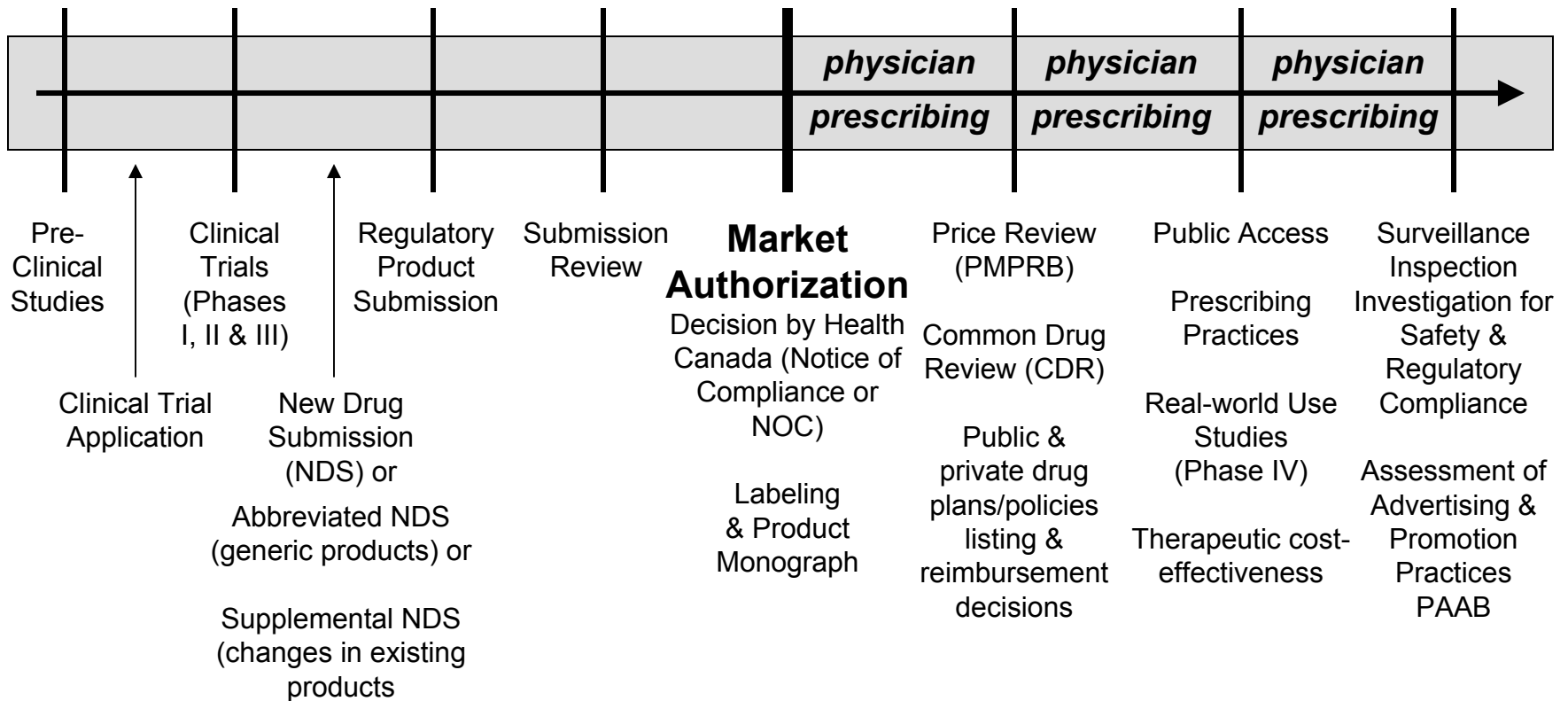
Global/domestic product innovation and research & development

Access and use by providers/consumers through the health care system

Pre-Market

Post-Market

...safety, quality, efficacy, therapeutic effectiveness, cost-effectiveness...



In addition to education & training, academics bring the following to social challenges (pharmacovigilance)

- State of the art knowledge
- Study design & implementation expertise
- Survey methodology expertise
- Rigorous and systematic data collection
- Data management and analysis skills
- Program evaluation expertise