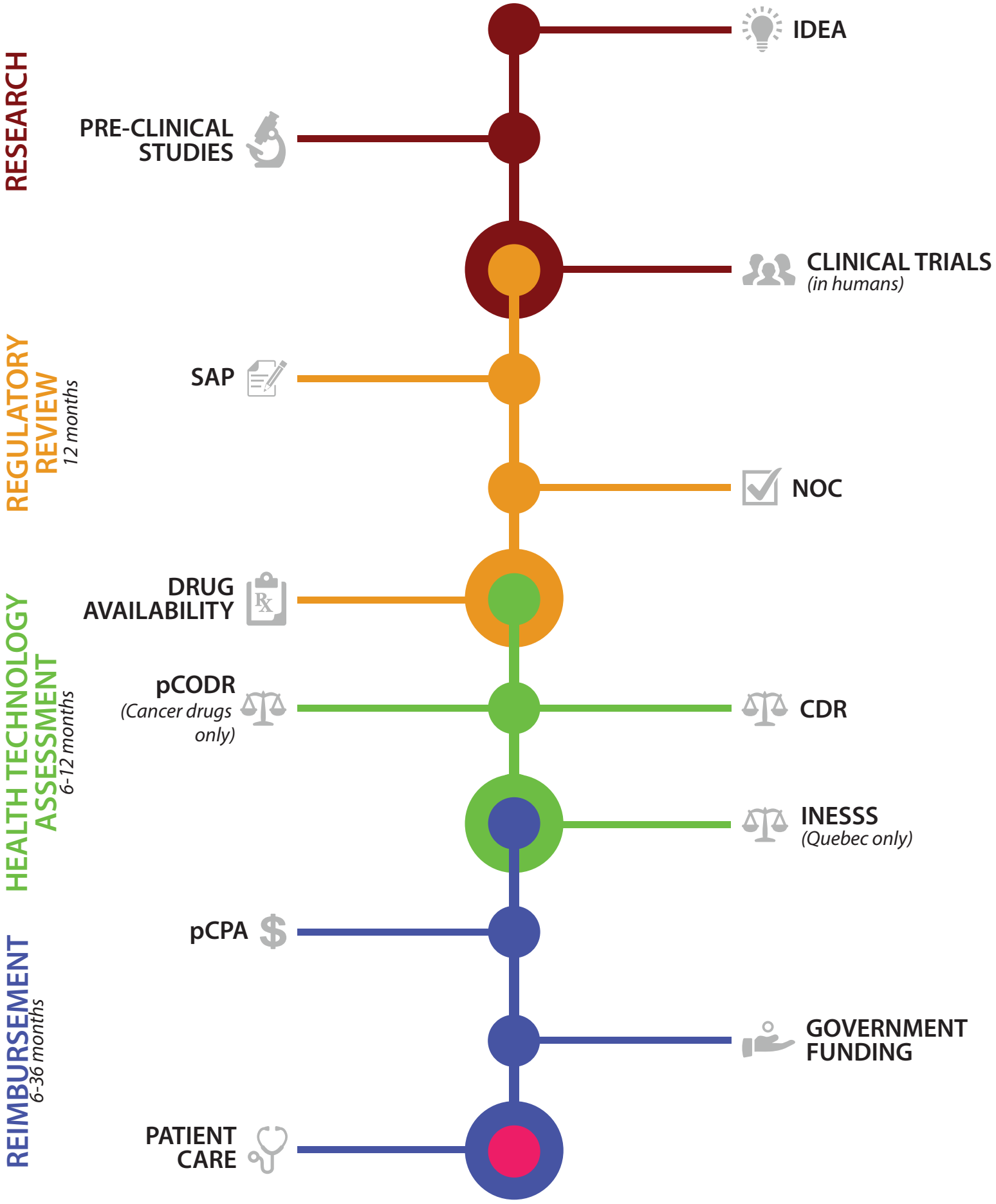
DRUG APPROVAL AND FUNDING PROCESS IN CANADA



DRUG APPROVAL AND FUNDING PROCESS IN CANADA

RESEARCH

Pre-Clinical Studies

- When researchers develop a new drug, before testing it in people they must first find out if it has the potential to cause serious harm
- Known as pre-clinical studies, these first tests on a drug are conducted in a laboratory using cells, tissue samples and animals
- If the results of these studies are promising, the next step is clinical trials conducted with human participants

Clinical Trials

Learn more

- Clinical trials offer patients a chance to take part in research that could improve their health and help others with the same condition or disease in the future
- Conducted in four phases, these studies help researchers assess and confirm the drug's safety, effectiveness and best dosage, identify any side effects, and compare it to commonly used treatments (if available) for the same disease or condition
- If clinical trials prove a drug's benefits outweigh its risks and a company wants to sell it in Canada, it applies to Health Canada (federal government) for regulatory approval, which includes submitting the results of clinical trials

REGULATORY REVIEW

Special Access Programme (SAP)

Learn more

- SAP is a Health Canada initiative that allows unapproved drugs into the country in certain circumstances
- SAP considers requests for access to drugs that are unavailable for sale in Canada, from physicians treating patients with serious or life-threatening conditions who have no other options
- There is no formal mechanism for patient input

Notice of Compliance (NOC) OR Notice of Compliance with Conditions (NOCc)

Learn more

- Through its regulatory process, Health Canada reviews new drugs for safety, efficacy and quality
- A NOC/NOCc is issued to a company following the satisfactory review of a submission for a new drug, authorizing approval to sell the drug in Canada
- There is no formal mechanism for patient input

Drug Availability

- Soon after a drug is approved for sale in Canada, the company begins making it available
- The drug is not yet funded by governments and can only be accessed by patients in need through private insurance or by paying out-of-pocket

DRUG APPROVAL AND FUNDING PROCESS IN CANADA

HEALTH TECHNOLOGY ASSESSMENT

Common Drug Review (CDR)

Learn more

- National review process for non-oncology drugs that focuses on the cost-effectiveness of a drug vs. current therapies
- CDR issues a recommendation to the government drug plans (except Quebec - see INESSS) as to whether or a not a drug should be publicly funded for patients who need access
- There is a formal mechanism for input from organized patient groups

pan-Canadian Oncology Drug Review (pCODR)

Learn more

- National review process for oncology drugs that focuses on the cost-effectiveness of a drug vs. current therapies
- pCODR issues a recommendation to the government drug plans (except Quebec - see INESSS) as to whether or a not a drug should be publicly funded for patients who need access
- There is a formal mechanism for input from organized patient groups and individual/groups of physicians

Institut national d'excellence en santé et en services sociaux (INESSS)

Learn more

- Quebec's review process to evaluate therapeutic value and cost-effectiveness of oncology and non-oncology drugs
- INESSS issues a recommendation to Quebec's Minister of Health and Social Services as to whether or not a drug should be publicly funded for patients who need access
- There is a formal mechanism for input from individual patients and patient groups, caregivers and physicians

REIMBURSEMENT

pan-Canadian Pharmaceutical Alliance (pCPA)

Learn more

- National mechanism designed to achieve greater value for government drug plans
- pCPA negotiates with a drug company to determine both the cost and criteria under which governments will pay for a medication, concluding with a Letter of Intent to fund the drug
- Drugs with a CDR/pCODR/INESSS recommendation are not necessarily invited into the pCPA process
- There is no formal mechanism for patient input

Government Funding

- Individual governments negotiate with the drug company to determine both the cost and criteria under which that government will pay for the drug, concluding with a Product Listing Agreement
- A Product Listing Agreement is typically modelled on the Letter of Intent negotiated through pCPA, but not always
- There is a formal mechanism for patient input only in Ontario and British Columbia