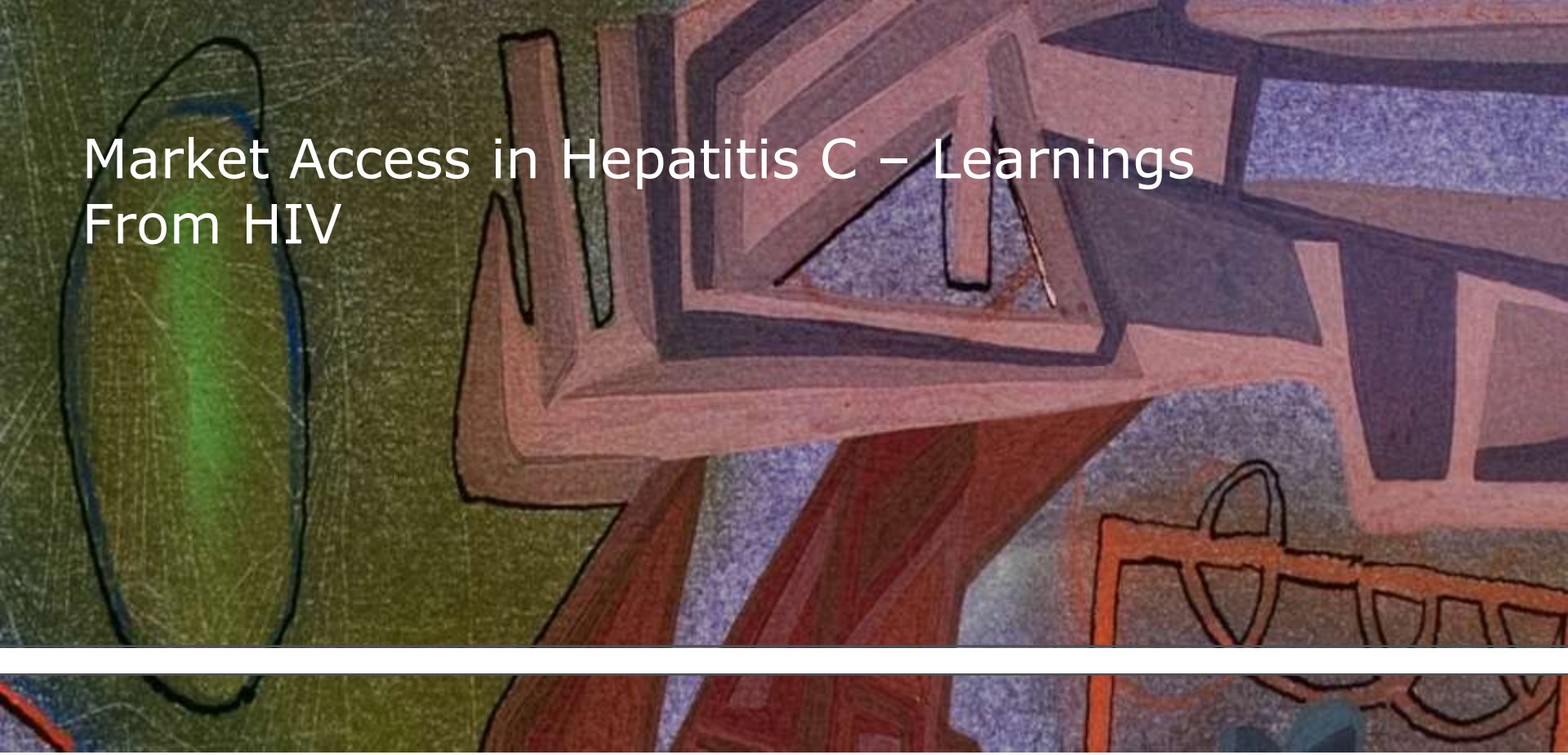


Market Access in Hepatitis C – Learnings From HIV

Allan F. Miranda Ph.D., MBA.

Therapeutic Lead Immunology and Virology- Government Affairs and Market Access

janssen

Our CREDO

Throughout our global organization we are bound together by a common focus on helping people

Our CREDO defines our commitment to…

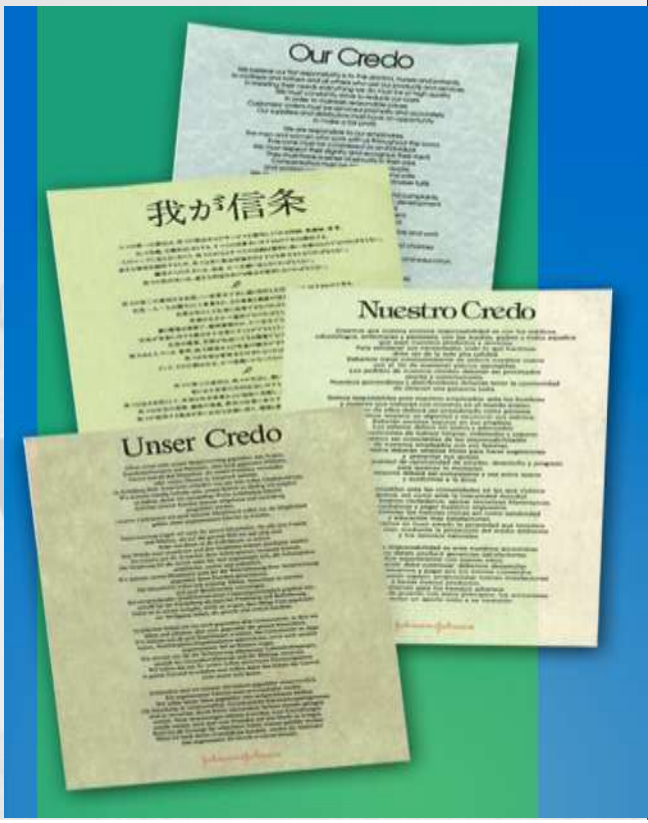
Customers,

Employees,

Communities

and our

Stockholders




EDURANT
(rilpivirine) tablets
PREZISTA
(darunavir) tablets
INTELENCE
(etravirine) tablets
janssen

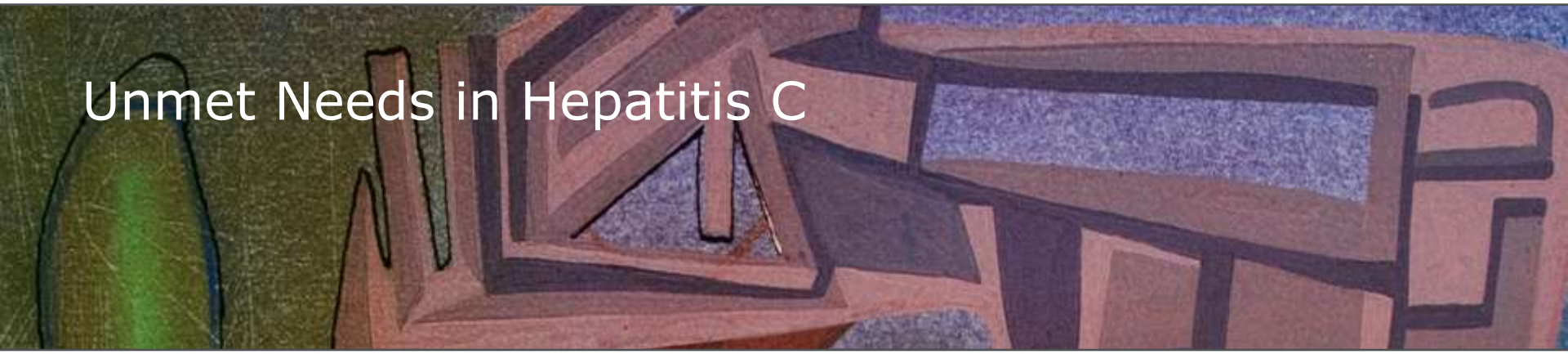
Our Credo in Action

- Simeprevir (Submitted to Health Canada-Priority Review)
  - Chronic hepatitis C infection for treatment naïve patients
  - Chronic hepatitis C infection for treatment experienced patients

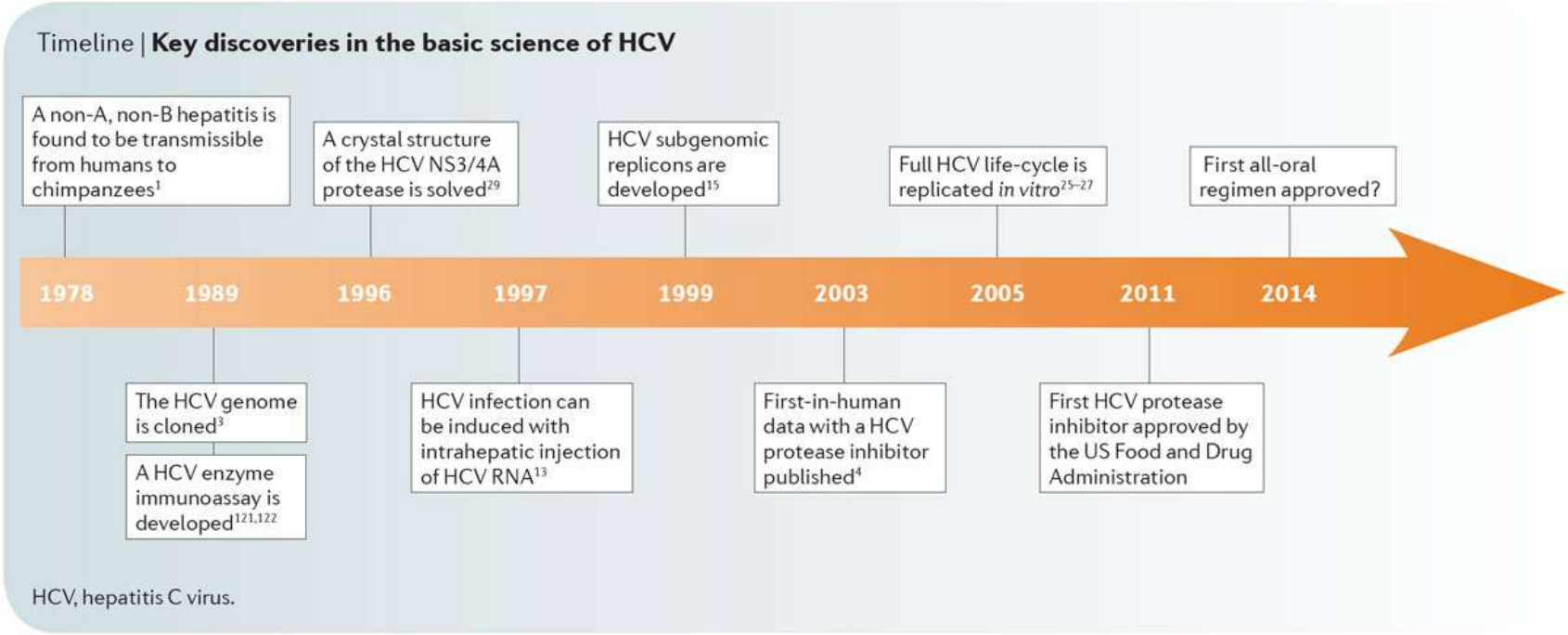
- TMC 207
  - Multidrug resistant (MDR) tuberculosis
  - First new mechanism of action in more than 40 years
  - First and only drug specifically indicated for MDR
  - Developed in partnership with the Global Alliance for TB Drug Development

Agenda

- Reimbursement Issues Impacting Hepatitis C
  - Contrasts with HIV
- Challenges and Opportunities


Unmet Needs in Hepatitis C

Timeline of Discovery Hepatitis C

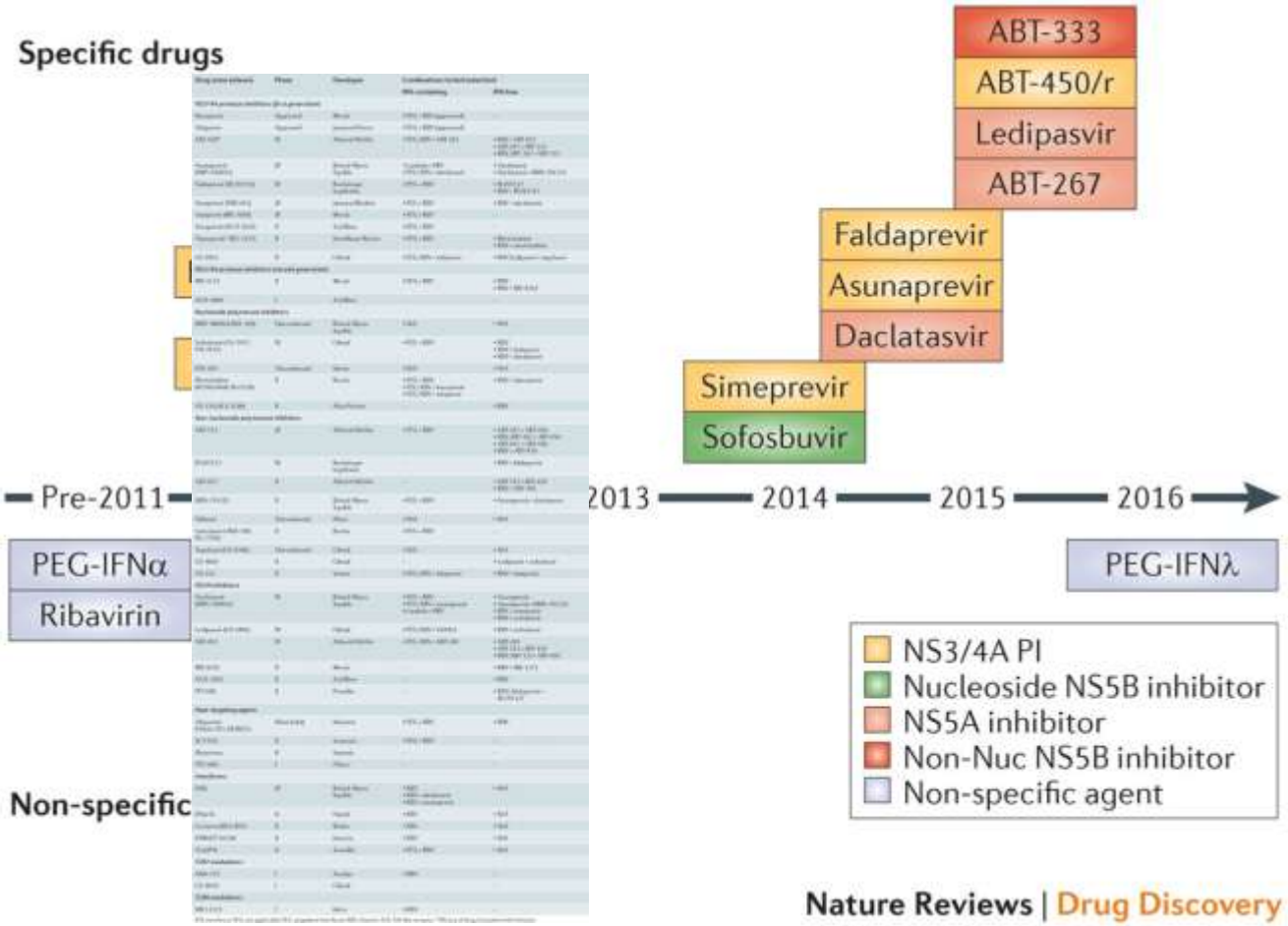


Related Reimbursement Issues

- Burden (financial and clinical) of disease is significant
  - Not all patients will progress to have significant liver disease
- Previous standard of care (PEG RIBA) provided the promise of a cure but was not associated with optimal outcomes
  - High cost, relatively low SVR rates, significant side effects, extended duration of therapy
- Existing Direct Acting Agents (DAA) in combination with PEG/RIBA provide a significant advance
  - Higher SVR rates
  - Incremental cost a concern for payers and side effects still a relevant issue for clinicians and patients

Number of Drugs in Development

Drugs in Development



Related Reimbursement Issues

Interim results from Cohort 2 of the COSMOS study evaluating Simeprevir and Sofosbuvir in HCV patients with METAVIR scores F3-F4

· In Hepatitis C patients with advanced liver fibrosis or cirrhosis (METAVIR F3 or F4) 12 weeks all oral treatment with simeprevir and sofosbuvir with or without ribavirin led to SVR4 rates of 96% and 100%, respectively

· Once-daily simeprevir and sofosbuvir with or without ribavirin was generally safe and well tolerated

Stockholm, Sweden - Medivir AB (OMX: MVIR) today announced interim results from the second Cohort in the ongoing COSMOS study evaluating a once daily combination of simeprevir and sofosbuvir in hard to cure hepatitis C (HCV) patients.

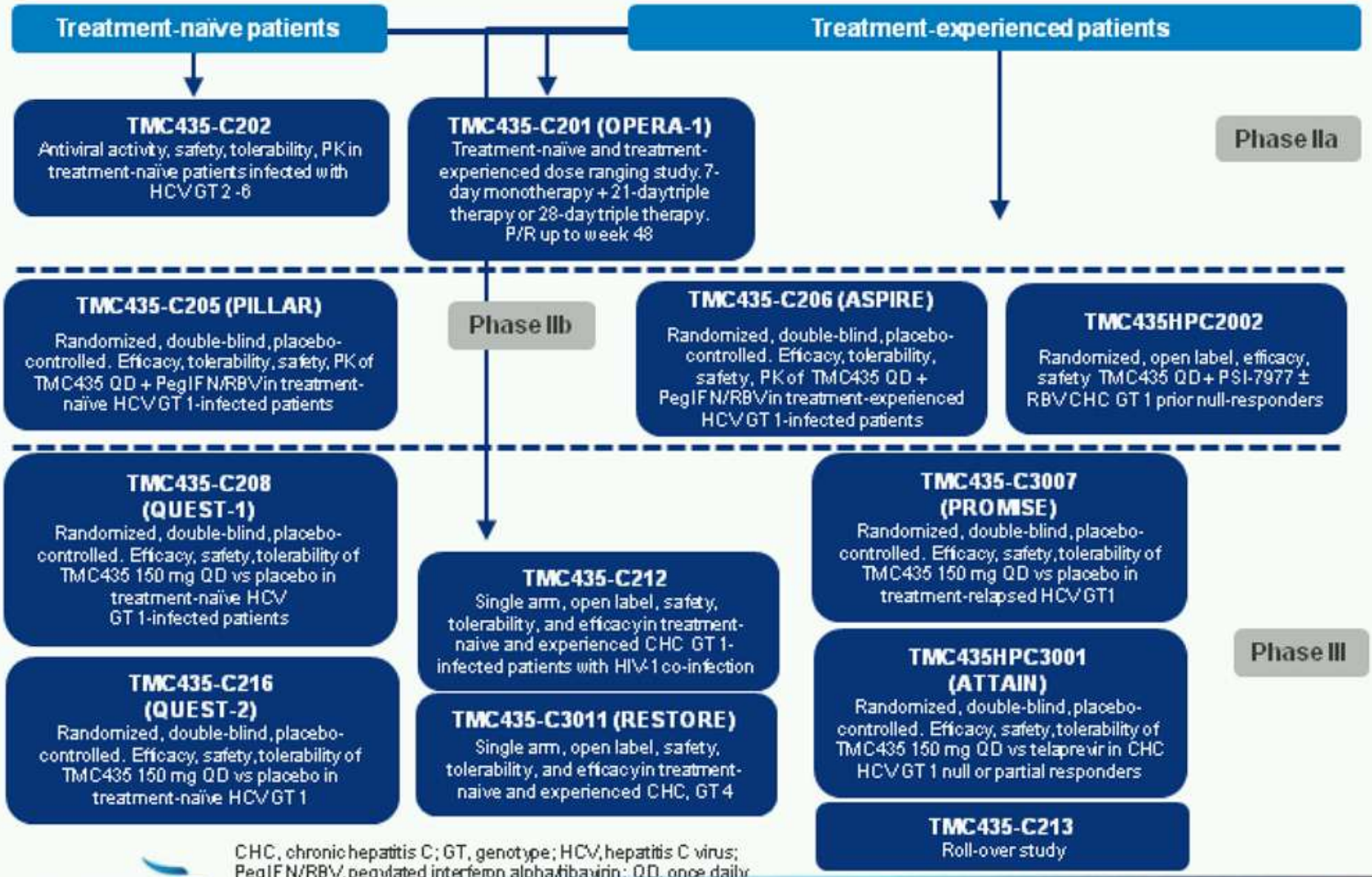
SVR4 results from the 12 week arms of Cohort 2, including treatment naïve or previous null responder HCV patients all with METAVIR score F3-F4 were reported. Treatment for 12 weeks with simeprevir and sofosbuvir, with or without ribavirin, led to SVR4 rates of 96% and 100%, respectively.

Interim results from Cohort 1 of the COSMOS study, which include only prior null responder HCV patients (METAVIR F0-F2) have been reported earlier and demonstrated SVR8 rates of 96% and 93% after 12 weeks treatment simeprevir and sofosbuvir with and without ribavirin, respectively.

  - Opportunity for real world data generation
- Complicated discussions with multiple commercial entities


Complexity of Clinical Development

Global clinical development of TMC435

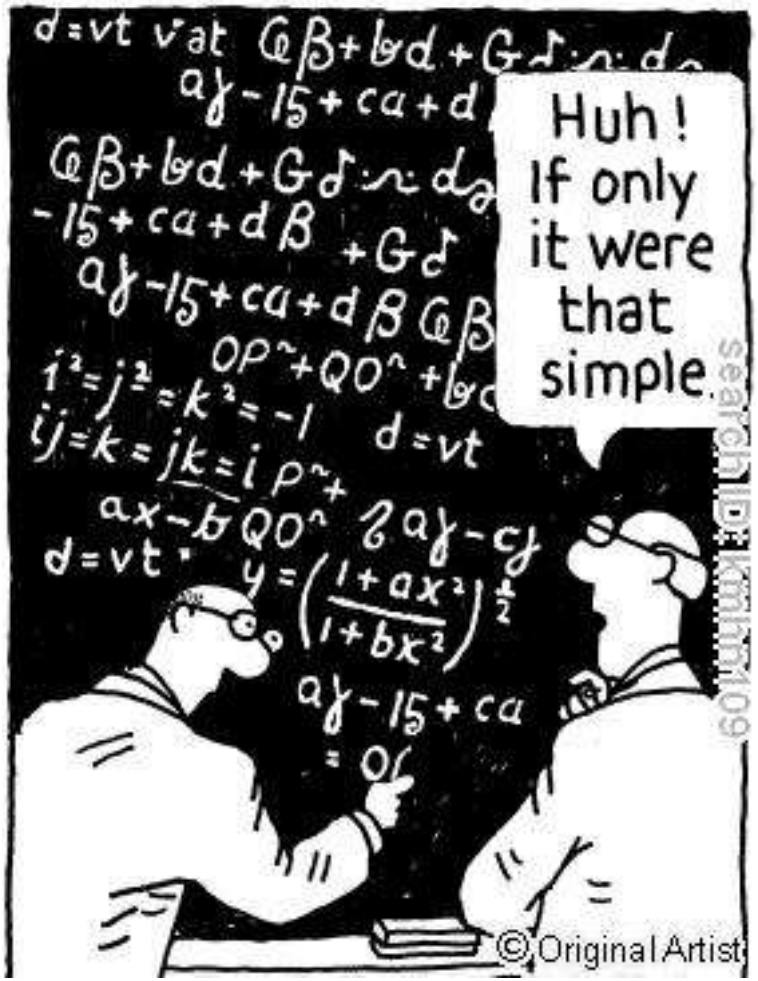


CHC, chronic hepatitis C; GT, genotype; HCV, hepatitis C virus; PegIFN/RBV, pegylated interferon alpha/ribavirin; QD, once daily

Related Reimbursement Issues

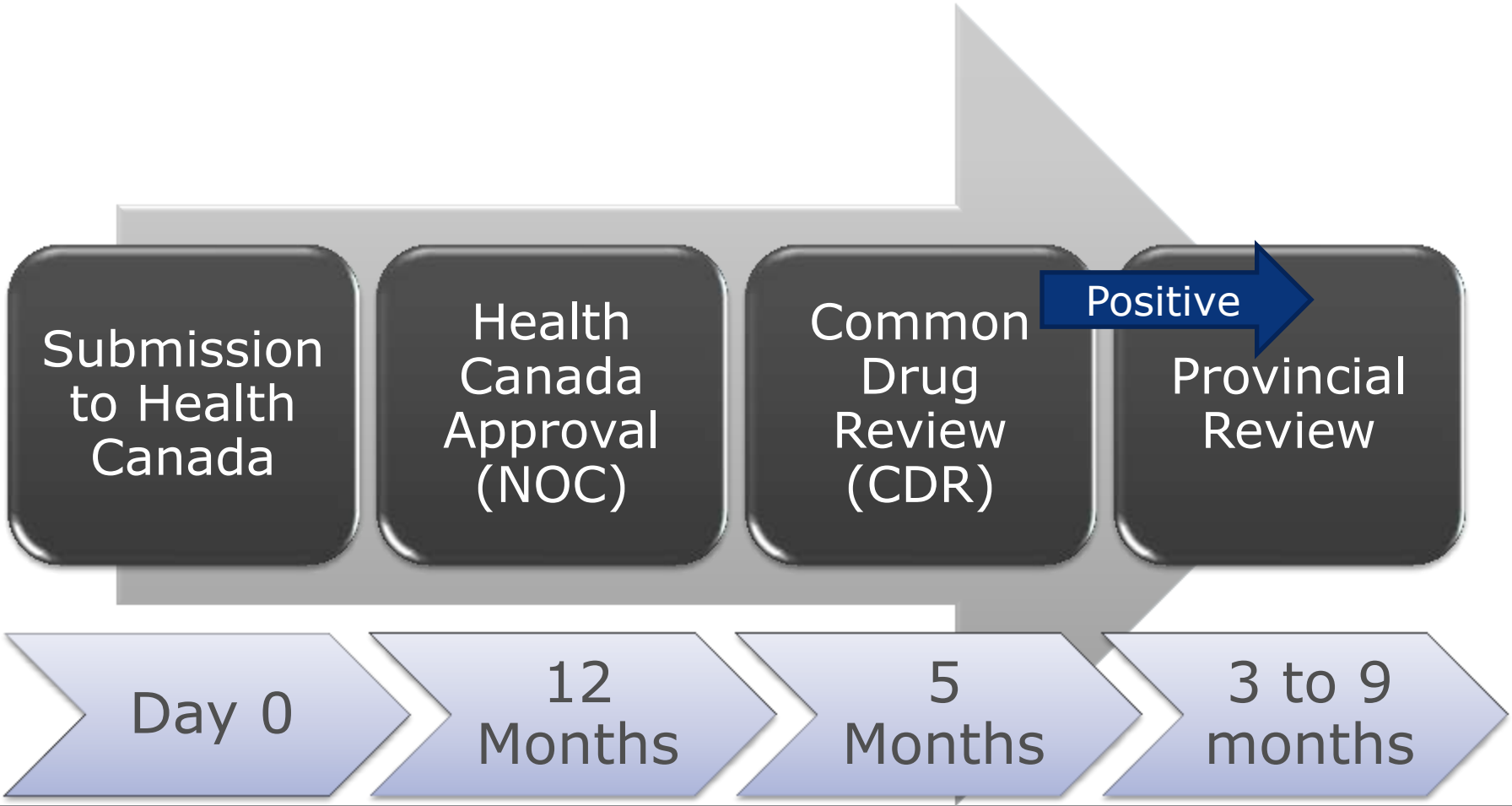
- Numerous patient subgroups complicate reimbursement for manufacturer and payers (E.g. naïve, treatment experienced, different genotypes, co-infect)
  - Trials needs to be powered appropriately to demonstrate benefit in patient subtypes
  - Payers faced with the challenge of reimbursing numerous drugs to cover all subtypes
- Data for subpopulations often matures post approval or after reimbursement for broad population
  - Complicated reimbursement criteria
  - Balancing clinical need with appropriate clinical evidence
- Including appropriate comparators within clinical trials
  - Rapid entry of drugs limits opportunities for H2H studies
  - Reduces opportunity for payers and clinicians to assess relative efficacy
    - Importance of indirect comparisons and real world evidence generation to make relevant comparisons

Reimbursement in Canada

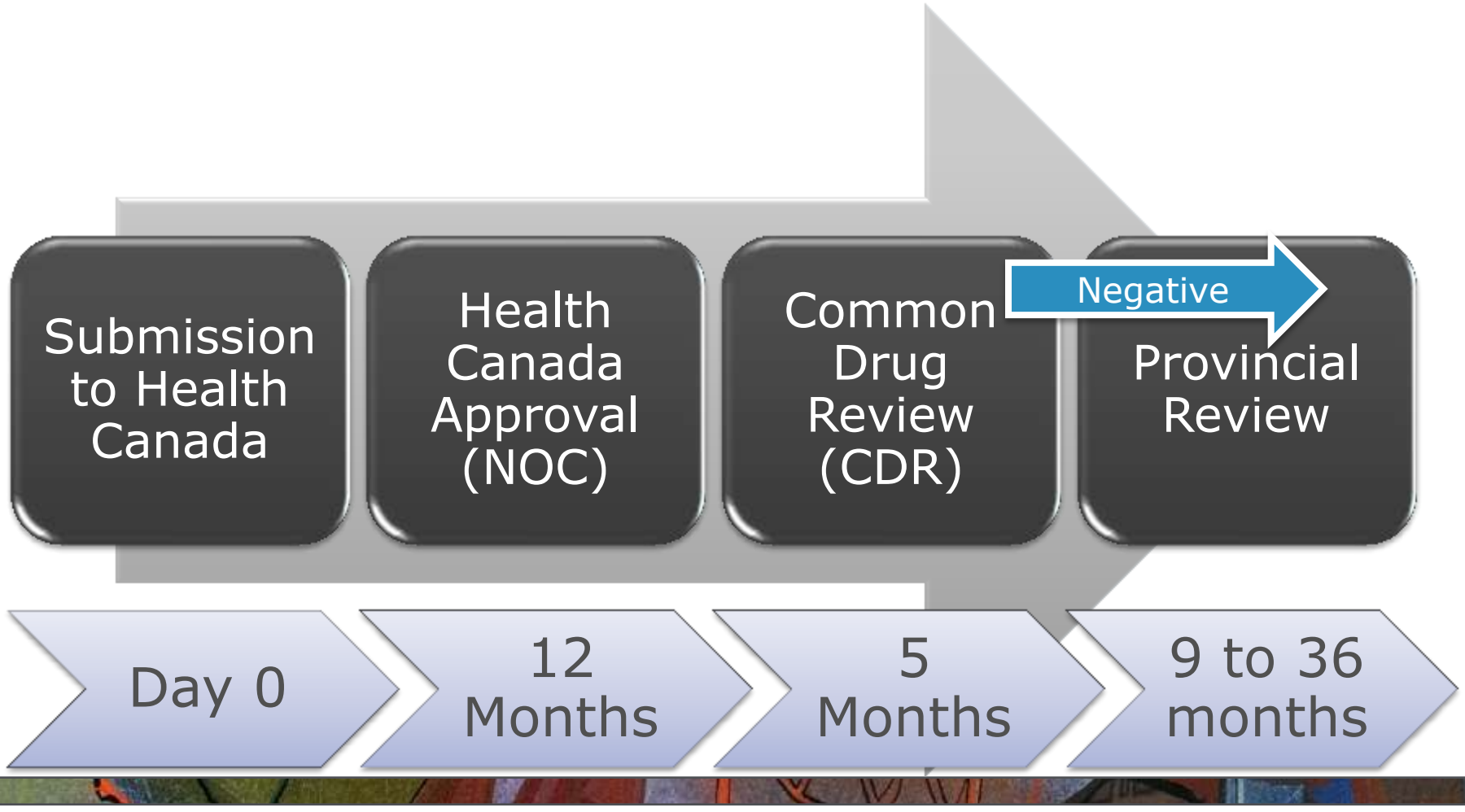


Reimbursement Process

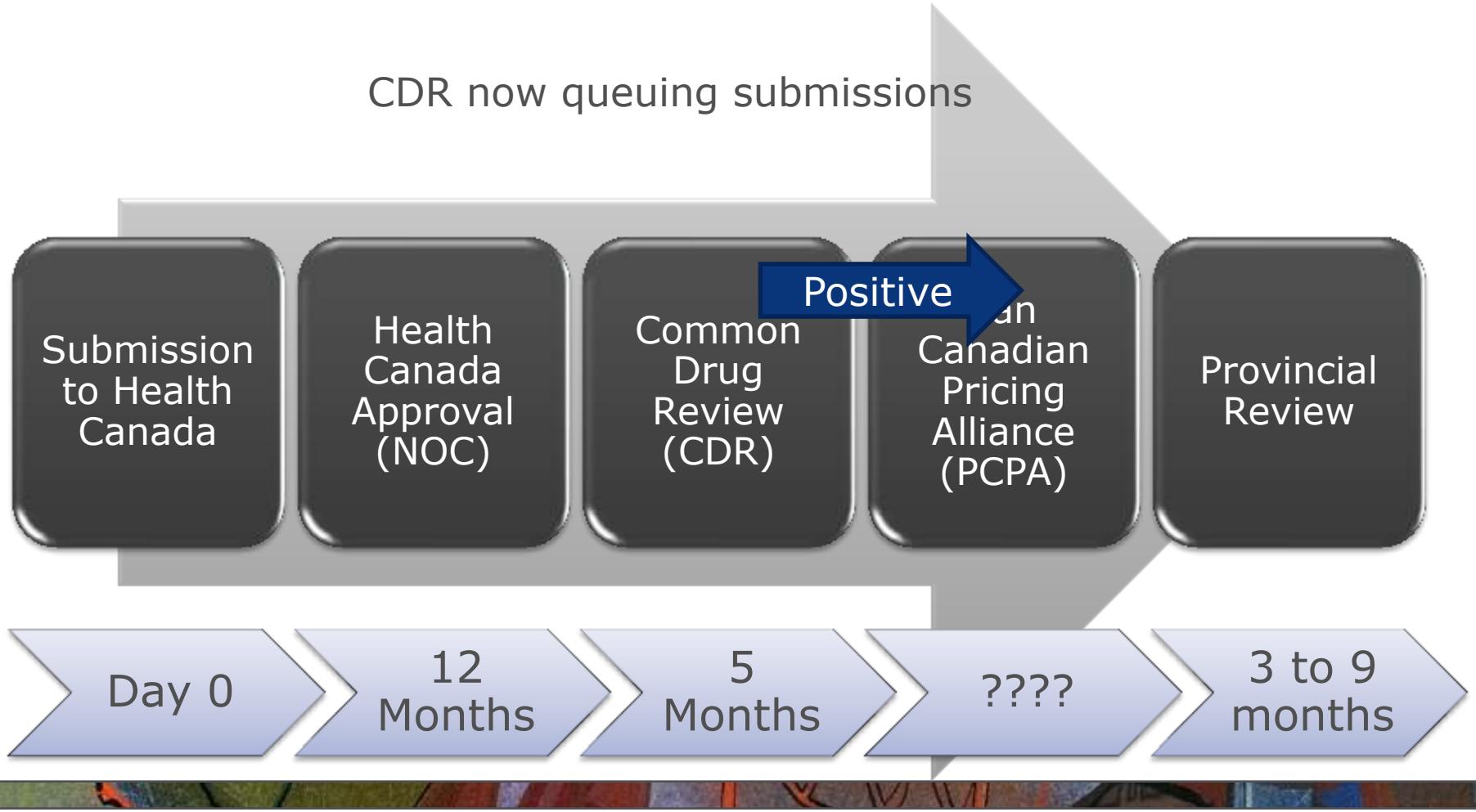
Multiple Approval Layers Impacts Access…



Multi Approval Layers…



And now another layer…Pan Canadian Pricing Alliance (PCPA)



Implications For Reimbursement

- Significant lag from approval to reimbursement
  - With DAA's already reimbursed the gap in therapy is not as large
- Typical formulary reimbursement process lacks ability to focus on Hepatitis C and results in significant burden for drug plans
  - Center of Excellence (BC/AB) approach in HIV has merit
- Significant differences in market access across the country
  - No clear ability to determine best therapy or context of new molecules versus previously reimbursed agents
    - CADTH Therapeutic Reviews

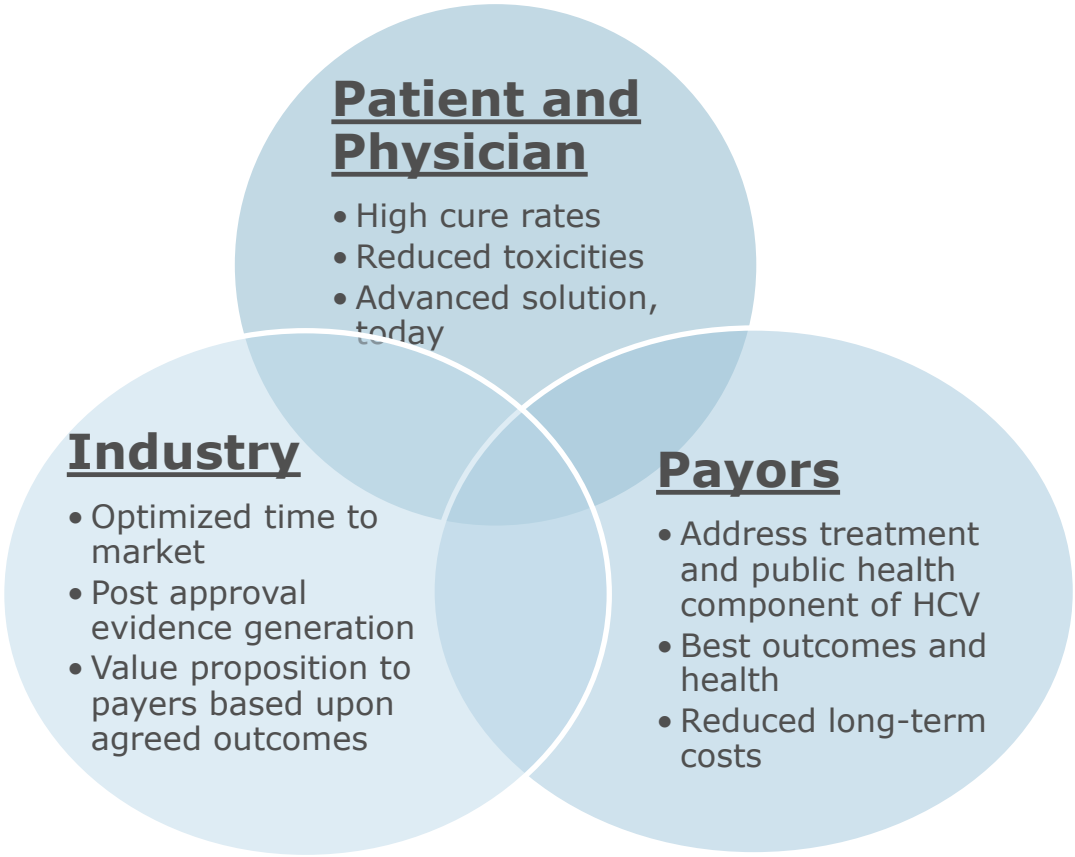
Comparing Key Factors in Market Access-HIV and Hepatitis C

Factor	HIV	Hepatitis C
Unmet medical need	+++	++
Number of drugs in development	++	+++
Complexity of Clinical Trials	++	+++
Complexity of reimbursement process	+	+++
Impact of Patient of Advocacy	+++	++

Opportunities

- Flexible frameworks for regulatory approval and measurement of cost effectiveness
  - Expedited reviews at Health Canada(DAA)
  - Indirect comparisons and real world measures of effectiveness
  - Incorporate patient and physician preference into assessment
  - Pay for performance approach with manufacturers
- Reimbursement assessment outside traditional Provincial Formulary Approach
  - Center of Excellence in HIV (BC, AB)- Parallels with Hepatitis C
- Treatment and prevention approach similar to HIV
  - Implementation of a preferred treatment regimen for all Hep C patients based on best outcomes
  - Best drug combination irrespective of manufacturer

Desired Outcome



Questions????