Cancer Drug Pipeline Tracking Information - 2015

Updated: August 20, 2015
Objectives of Update

- Review oncology drugs in the pipeline being tracked to July 31, 2015
- Identify key trends

Purpose of Tracking

The pCODR Pipeline Tracker systematically identifies and monitors novel oncology drugs and new indications for pre-existing oncology drugs for the purposes of:

- Gaining awareness of emerging trends in oncology treatment
- Assisting provincial drug programs, cancer agencies and pCODR with proactive health system planning and program operations such as resource allocation, scheduling, et cetera.
- Identifying potential tumour group submissions
Algorithm for Pipeline Tracking

1. Systemic Identification
   - Manufacturers survey
   - AHRQ Horizon Scanning
   - NIHR Horizon Scanning
   - FDA Hematology/Oncology (Cancer) Approvals
   - UK Medicines Information
   - pCODR Provincial Advisory Group

2. Filtration & Selection
   - Additional Information from NCIC CTG, ASCO, etc.
   - Assessment according to pCODR’s inclusion & exclusion criteria
   - pCODR’s anticipated submissions list
   - HC NOC

3. Database Input
   - Drug Generic name
   - Indication
   - Tumour Group Panel
   - New Drug or New Indication
   - Companion Test
   - Route of Administration
   - Trial Status
   - Information Source
   - Reason, if no longer in pipeline

4. Reporting of Aggregate Data to
   - pCODR Provincial Advisory Group
   - pCODR Advisory Committee
   - pCODR Expert Review Committee

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## Inclusion and Exclusion Criteria

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<thead>
<tr>
<th>Inclusion Criteria (and)</th>
<th>Exclusion Criteria (or)</th>
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<tbody>
<tr>
<td>1. Oncology drug for active treatment of cancer</td>
<td>1. Oncology drug for symptom management or supportive treatment only</td>
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<tr>
<td>2. New chemical entity, vaccine or biology/targeted therapy or New indication with no NOC</td>
<td>2. NOC received or pending and expected pCODR submission</td>
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<td>3. In Phase 2 or 3 clinical trial</td>
<td>3. In Phase 1 clinical trial</td>
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<td>4. Multi-national trial location with at least one participating centre in Canada</td>
<td>4. Small local trial with no participating centres in Canada or US</td>
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<td>5. Small local company overseas</td>
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Pipeline Data Sources

- **Primary Source:** pCODR’s annual survey to manufacturers

- **Other sources include monthly scan of:**
  - Agency for Healthcare Research and Quality Healthcare Horizon Scanning System
  - National Institute for Health Research Horizon Scanning Research & Intelligence Centre
  - U.S. Food and Drug Administration - Hematology/Oncology (Cancer) Approvals & Safety Notifications
  - Provincial Tumour Group through pCODR’s Provincial Advisory Group
Overview of Current Pipeline Drugs Tracked by pCODR

- 32 manufacturers
- 149 distinct drugs
  - 97 new molecular entities
  - 52 pre-existing drugs
- 305 drug-indication pairs
  - 217 new molecular entities
  - 88 new indications for pre-existing drugs
Distribution by Route of Administration

Of the 149 Distinct Drugs:

- **Intravenous**: 70 (46%)
- **Oral**: 70 (46%)
- **Intradermal**: 3 (2%)
- **Subcutaneous**: 7 (5%)
- **Intramuscular**: 1 (1%)
Distribution by Trial Status

Of the 305 Drug-Indication Pairs:

- Phase 2: 137 (45%)
- Phase 3: 160 (52%)
- Completed or Unknown: 8 (3%)
Distribution by Companion Diagnostic Tests

- None: 262 (86%)
- Companion Diagnostic Tests: 43 (14%)

Drug Indication Pairs with Companion Tests:

- ALK
- BCR-ABL T315I
- BRAF V600
- BRCA
- EGFR
- ER/PR
- FGFR2
- FLT3
- HER2 Breast
- HER2 GI
- HER2 Lung
- KRAS
- PD-L1
- Other
Distribution by Tumour Site

Drug Indication Pairs

- Breast
- Endocrine
- Gastrointestinal
- Genitourinary
- Gynecology
- Head and Neck
- Leukemia
- Lung
- Lymphoma and Myeloma
- Melanoma
- Neurological
- Sarcoma
- Other

- 2014
- 2015

Submissions Received 2011 to July 31, 2015

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Some Factors Influencing Submissions to pCODR

**Timeline**
Potential submissions in next 12 months to around 5 years

- Manufacturers decide to submit after phase 2 trial or after interim analysis of phase 3 trial
- Manufacturer conducts subgroup analysis prior to submitting

**Numbers**
Not all will result in a submission to pCODR

- Manufacturer decides not to seek licensing in Canada
- Manufacturer decides not to submit for national funding review
- Failed to meet trial outcomes or serious adverse events halts further development
- Several drug-indication pairs may be combined as one single submission to Health Canada and/or pCODR
- There are drugs in the pipeline from smaller biotech companies not tracked by pCODR’s
Key Messages

- Hematology (Leukemia, Lymphoma & Myeloma) still largest number
- Distribution of oral drugs and intravenous drugs are close to equal
- Not all drug-indication pairs tracked by pCODR will result in a submission
- There are a number of small biotech companies not being tracked by pCODR