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Comparison of cancer drug approvals among international regulatory bodies

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Disclosure

- No conflicts of interests to disclose

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Why drug approvals?

- The therapeutic care of cancer patients is significantly impacted by timely access to drugs that improve survival and overall patient outcomes
- The path of a cancer drug from discovery to clinic is long and arduous
- Cancer drug approval process is a key component of drug access, critical to ensure safe and effective therapies for patients

Primary Aim:

Examine drug approval process and time to drug approval across international regulatory bodies

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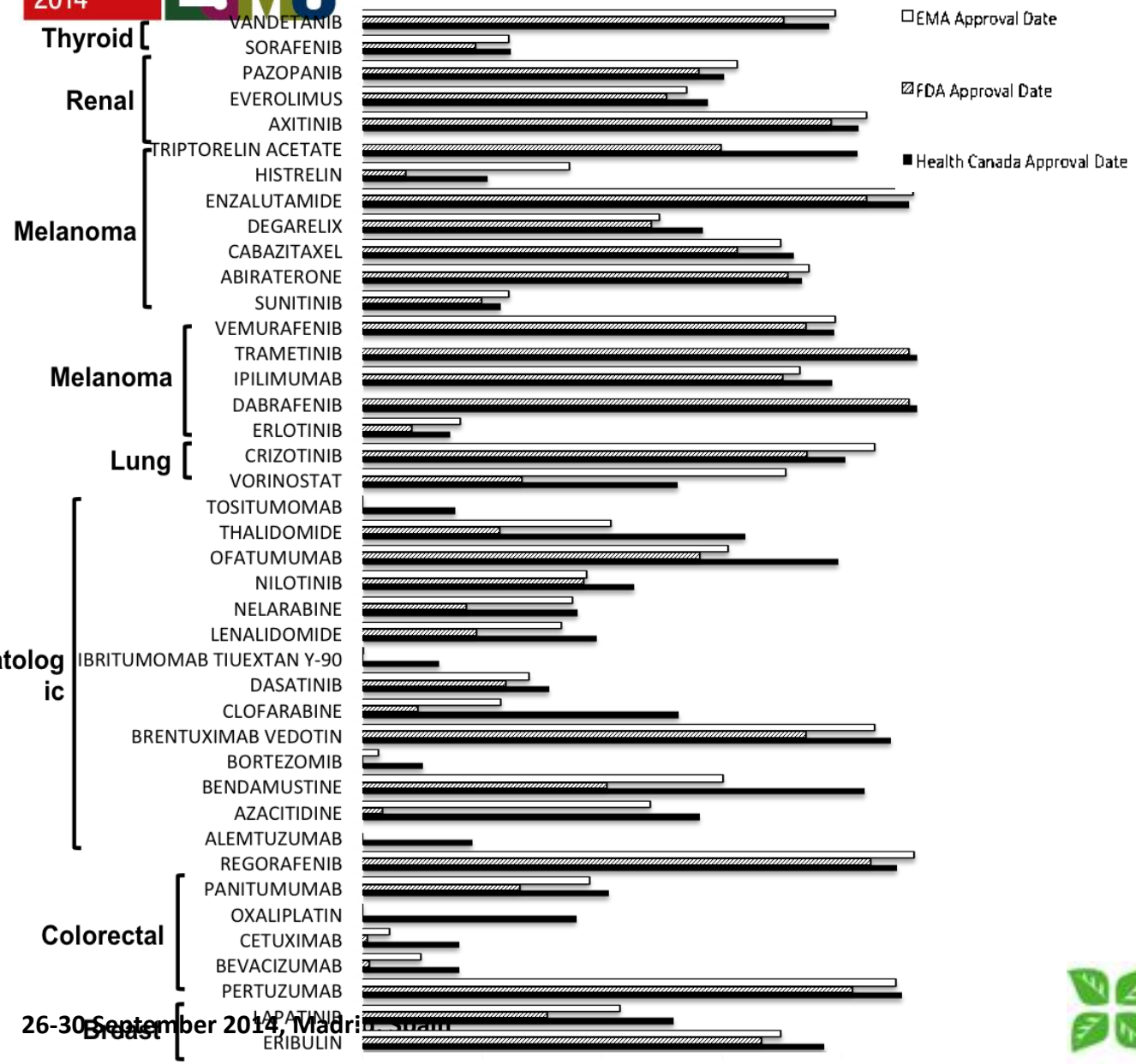
Methods

- Health Canada Drug Product Database was surveyed for all currently marketed therapies with class designation 'Antineoplastics' and approved any time after January 1, 2005 – June 1, 2013 .
- Identified 41 antineoplastic agents that met the study criteria.
- For this list of drugs, data were obtained on submission and approval dates by Health Canada, as well as the FDA and EMA.
- Dates for submissions and approvals only include the first indication the drug was approved for and not supplemental submissions or additional approvals.
- Only active treatment drugs were surveyed, not drugs deemed for supportive oncology care.
- Statistical analysis were performed using two-tailed t-test for comparison of time to drug approvals between two groups and one-way ANOVA for comparison across all three agencies.

Study Terms

- Drug approval dates: difference in time (months) in drug approval by regulatory bodies with respect to absolute dates
  - Is related to when new drug application submitters file for each individual agency
- Time to approval (TTA): time from initial drug submission by sponsor to approval by federal regulatory agency

Results: Drug approval dates



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Limitations

- Analysis was limited by the consideration of only initial drug approvals in Canada and not supplementary drug approvals, which constitute a large portion of cancer drug approvals.
- Indeed, the trends observed may be different when considering time to supplementary drug approval once the drug has initially been given regulatory approval.
- Approval times are not the only dimension to drug access. Cancer drug approval times may not necessarily precede swift regulation of drug costs and coverage (Shah RR et al, 2013), yet early approval times are a salient aspect of drug access.

Concluding Remarks

- Our main aim as clinicians is to ensure that patients are given an opportunity to receive proven treatment in a timely manner.

- Timely access to cancer therapies is multi-factorial, and includes efficient regulatory approval:
  - The regulatory approval process is needed for countries/regions to ensure safety and efficacy for newer drugs.
- However, it is important need to balance due diligence to review appropriate treatment by regulatory agencies and providing treatment to our patients that is effective.

- This study prompts the need for a **dialogue** amongst industry, regulatory agencies, patient bodies, research community and oncology professionals on how best we can reduce the time to approval while ensuring safety for approved drugs. Cancer drug access process stands to benefit from **a coordinated international approach** to reduce the disparity in time to access new drugs around the world.

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Questions?

Appendix A: Drug approval processes among federal regulatory bodies

Health Canada	FDA	EMA
Health Canada is the regulatory body responsible for conducting a review process and authorizing a therapeutic agent for marketing. A sponsor, usually the pharmaceutical company that manufactures the drug, files a "New Drug Submission" with the Therapeutic Products Directorate (TPD) to thoroughly assess the safety, efficacy and quality of a drug. Once Health Canada approves the product for sale in Canada, the Notice of Compliance (NOC) is issued to the sponsor. If there is insufficient evidence to support the safety and efficacy of the drug, the TPD will not grant market authorization (Health Canada Website, 2013). This federal review process can take one to two or more years.	The United States Food and Drug Administration (FDA) is responsible for ensuring Americans have access to safe and effective drugs. Sponsors send the Center for Drug Evaluation and Research (CDER) evidence to support approval of their drug product through a "New Drug Application" or "Biologies License Application". The FDA's CDER evaluates new drugs before they can be approved for marketing in the United States	Drug approvals require a two-step process: first, once a sponsor submits an application for approval of a new drug, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) must issue a positive opinion on marketing authorization. Subsequently, the European Commission must adopt that opinion. Other substantial administrative details and obstacles pertaining to differences in language barriers of member countries also confound this process.

Appendix B: sample drug approvals

- Among all drugs assessed, cabazitaxel (Jevtana®), approved for metastatic prostate cancer, was associated with the shortest TTA by the FDA at only 17 days. In Canada and Europe, the TTAs for cabazitaxel were 11.63 and 11.03 months, respectively
- There was no significant difference in TTA between Health Canada and the EMA ($\bar{x}$ = 3.43 months, p=0.446). Azactidine (Vidaza®), approved for hematological malignancies, had the greatest delay (66.1 months) between FDA and Health Canada approval. The EMA approved azactidine 10.3 months earlier than Health Canada but 55.8 months following FDA approval.