# DARWIN EU® - Incidence rates of venous thromboembolic events in individuals with selected cancers

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## INTRODUCTION

- **Individuals with cancer have a higher risk of venous thromboembolism** (VT) than those without.[1]
- VT remains a major cause of **mortality** among individuals with cancer[2].
- The incidence rates (IRs) **vary** across populations and cancer types and are influenced by patient characteristics, treatments, and the stage of cancer at diagnosis.[3]
- When evaluating a potential safety signal associated with a novel cancer treatment, reliable, **up-to-date information on background VT rates in individuals with cancer is crucial**.

## OBJECTIVE

**To estimate the IRs of VT among adults with newly diagnosed cancers.**

## METHODS

- Multi-center **cohort study** (2016–2022)
- **Nine European data sources** from eight European countries:
  1. **Belgium (IQVIA LPD)**
  2. **Denmark (DK-DHR)**
  3. **Estonia (EBB)**
  4. **Finland (FinOMOP-THL)**
  5. **Germany (IQVIA DA)**
  6. **The Netherlands (IPCI)**
  7. **Spain (SIDIAP)**
  8. **The UK (CPRD GOLD & UK Biobank).**
- Individuals aged ≥18 years with a **primary incident diagnosis of one of the selected cancers**: bone, brain, breast, colorectal, corpus uteri, kidney, leukaemia and lymphoma, liver, lung, melanoma, oesophageal, ovary, pancreas, prostate, and stomach (excluding non-melanoma skin cancer).
- **VT outcomes**: deep vein thrombosis (DVT), pulmonary embolism (PE), composite DVT and PE, pelvic venous thrombosis (PVT), splanchnic vein thrombosis (SVT), retinal vein thrombosis (RVT), and disseminated intravascular coagulation (DIC).
- **Follow-up**
  - Start: the date of cancer diagnosis
  - End: first occurrence of the outcome, the end of the prespecified follow-up period (one or two years), loss to follow-up, the end of data availability, or the date of death.
- **Crude IRs per 100,000 person-years (PY)** with 95% confidence intervals (CIs) for thromboembolic events were estimated at one and two years after cancer diagnosis.
- Each cancer type and outcome was analysed **separately**.
- **Random-effects meta-analysis** was applied to the overall crude IRs to obtain pooled IRs.

## RESULTS

- A total **of 975,962** adults with cancer included.
- Overall, **47,076 thromboembolic events** occurred within one year of cancer diagnosis, and 58,979 within two years.
- The highest IRs of thromboembolic events were observed in **pancreatic, oesophageal, liver, stomach, lung, brain,** and **ovarian** cancers.
- **Composite PE and DVT** was the most common event across all selected cancers, except for liver cancer, with combined IRs [95% CI] per 100,000 PY ranging from 597 [491–726] in melanoma to 11,607 [7,574–17,787] in pancreatic cancer (**Figure 1**).
- Among individual outcomes **PE** was generally the second most frequent event across all selected cancer types, followed by **DVT**.
- **SVT** was the most common thromboembolic outcome in **liver cancer**, with a combined IR of 7,448 [1,858–13,039] per 100,000 PY.

## RESULTS

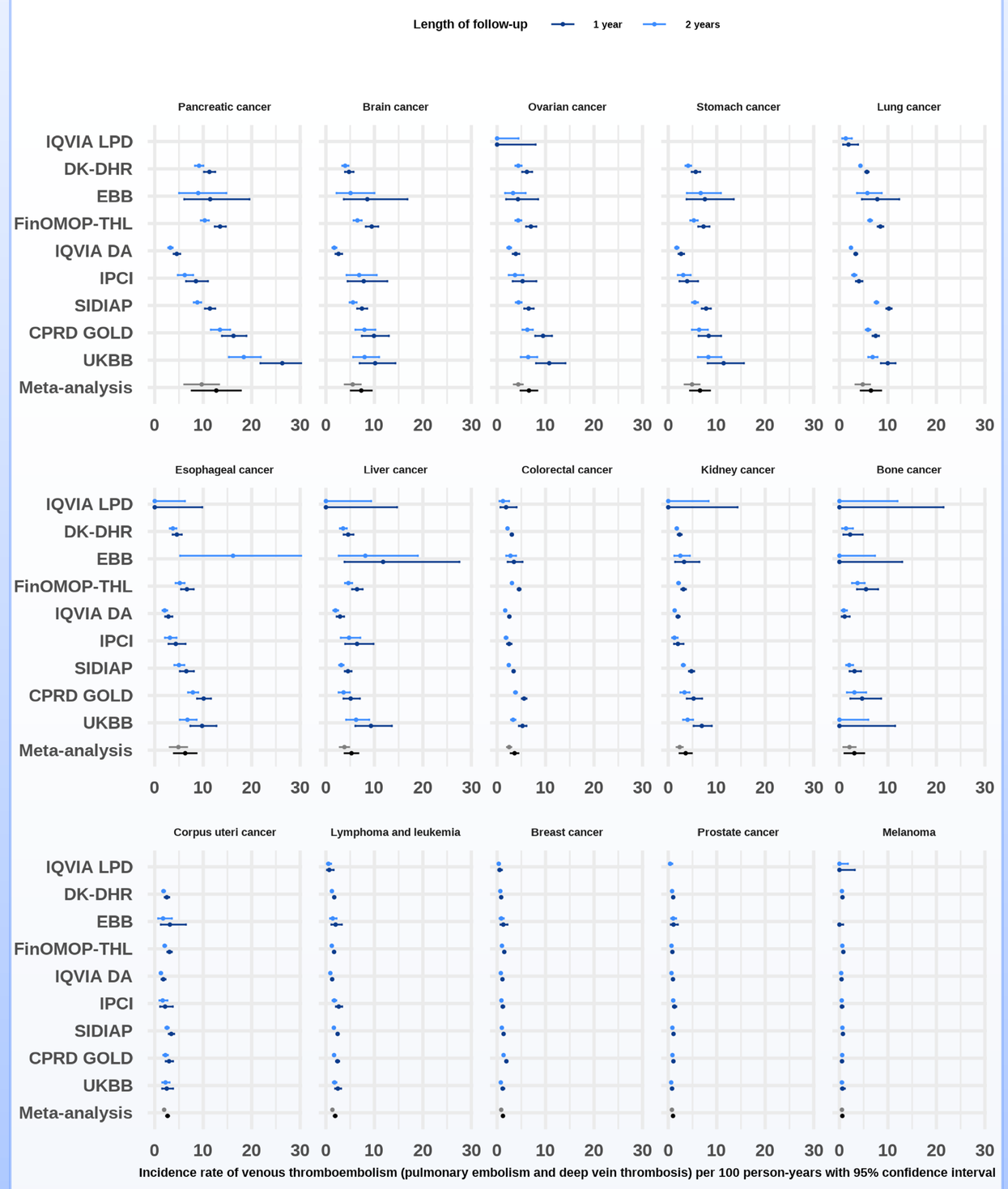


**Figure 1.** Meta-analysis of IRs with 95% CI of composite of PE and DVT per 100 PY one year and two years after cancer diagnosis.

## CONCLUSIONS

- **PE** and **DVT**, and their **composite** outcome, were the most frequently observed thromboembolic events among individuals with selected cancers.
- SVT was the most common outcome in individuals with liver cancer.
- The highest IRs of thromboembolic events were observed in individuals with **gastrointestinal** cancers.
- The **variation** in IRs across cancer types highlights the importance of considering cancer-specific and patient-level characteristics when contextualising the risk of VT.

## REFERENCES

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2. Wang T, Li A, Garcia D. Managing thrombosis in cancer patients. Research and Practice in Thrombosis and Haemostasis. 2018 July 1;2(3):429–38.

3. Timp JF, Braekkan SK, Versteeg HH, Cannegieter SC. Epidemiology of cancer-associated venous thrombosis. Blood. 2013 Sept 5;122(10):1712–23.

## DISCLOSURE

This study was funded by the European Medicine Agency (EMA) and performed via DARWIN EU® (EUPAS1000000440). EMA was involved in conceiving the research objectives, and reviewing the study protocol and the study report including the results. Data partners do not have and investigator role. They execute analytical code at their respective data sources, review, and approve their results. This communication represents the DARWIN EU® Coordination Centre only and cannot be interpreted as reflecting those of the EMA or the European Medicines Regulatory Network.

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