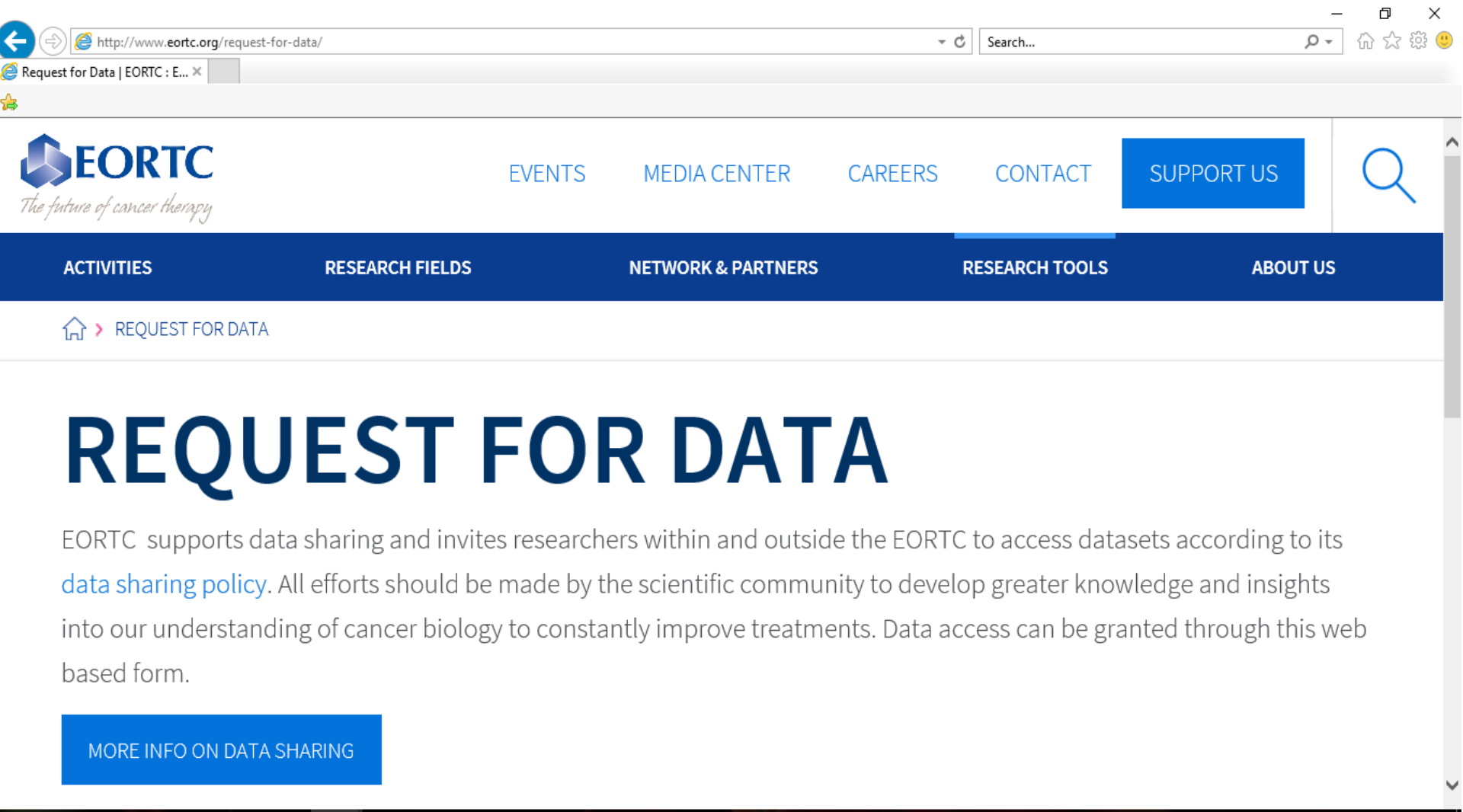
Data Sharing at EORTC

Laurence Collette, PhD
Head of Statistics Department
EORTC Headquarters, Brussels, Belgium

Yes

we do share our data!

EORTC Data Sharing Policy (POL008) effective since October 2001



How we are willing to share data

- **Collaboration model**
- Clinical trials are complex
  - Study protocol and amendments
  - Data coding conventions
  - Updates since final publication
  - Statistical analysis plan

- We want our data to be used for good research
  - Close collaboration is needed to ensure that the data are well understood
  - There are so many ways of making the data speak…

How we share the data technically

- The data are ***de-identified***
- A copy of the database is **physically sent to the researcher via a secure password protected portal (eg. Filebox)**
- We follow-up the projects closely to avoid
  - further dissemination of copies of the data
  - uncontrolled use of our data

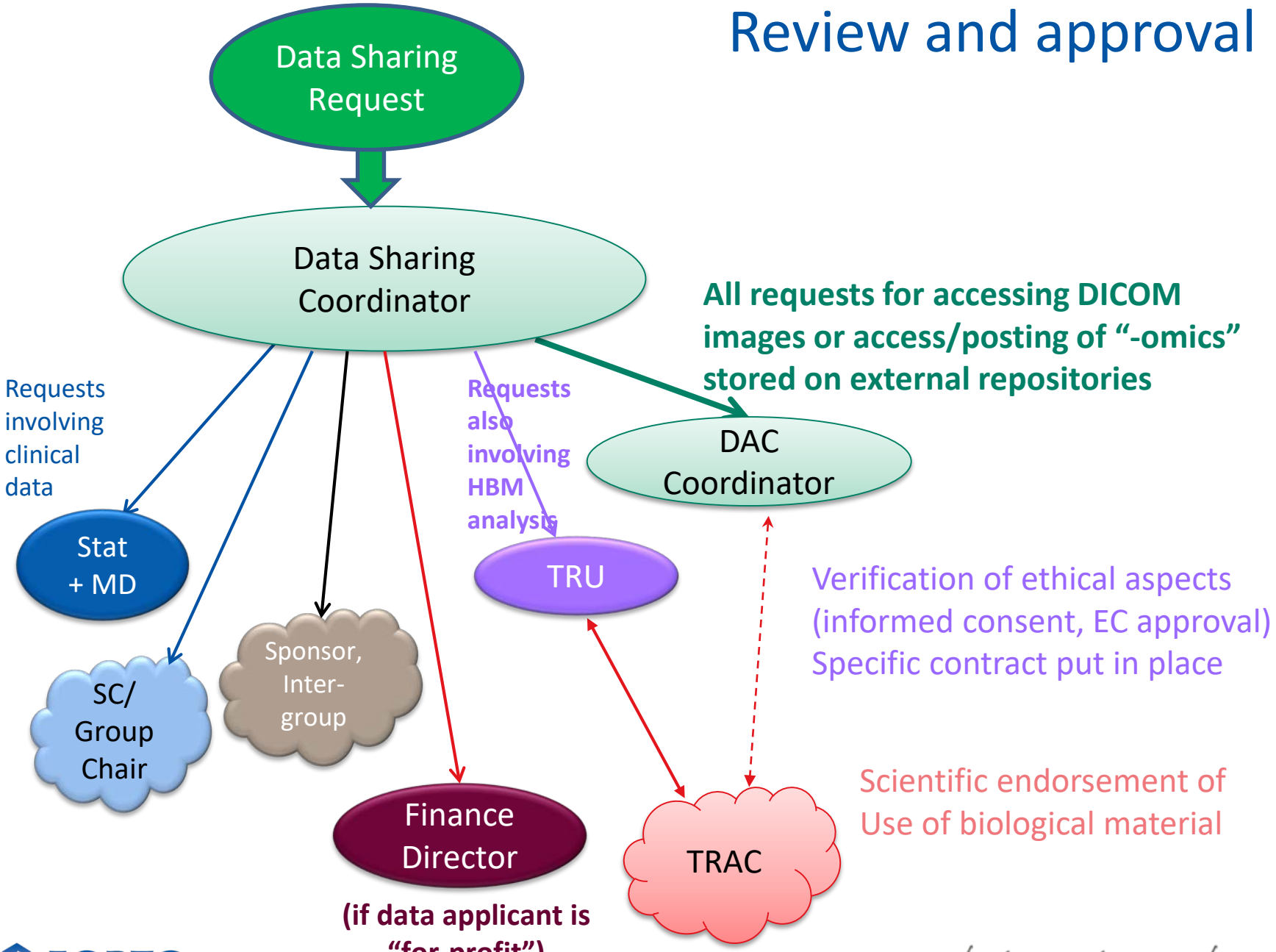
Data sharing at EORTC

Studies are available AFTER primary publication

Formal data request (online form)

- Description of the research
- Brief statistical analysis plan (SAP) and/or research protocol
- Curriculum Vitae of the methodologist in charge
- Publication plan
- Terms of use (contract) agreed and signed
    - Data to be used solely for the purpose of the defined project
    - Publications sent to EORTC prior to submission
    - Acknowledgement to EORTC
    - Protection of the confidentiality of the data!!
    - **Contract** if request of tissue/images/sensitive data
- So far at no cost if academic applicant

Review and approval



EORTC

The future of cancer therapy

Terms related to authorship

At time of request, declare

- Publication and posting plan
- Whether the publication will be **published on behalf of EORTC and/or co-authored by an EORTC staff (depending on level of involvement**

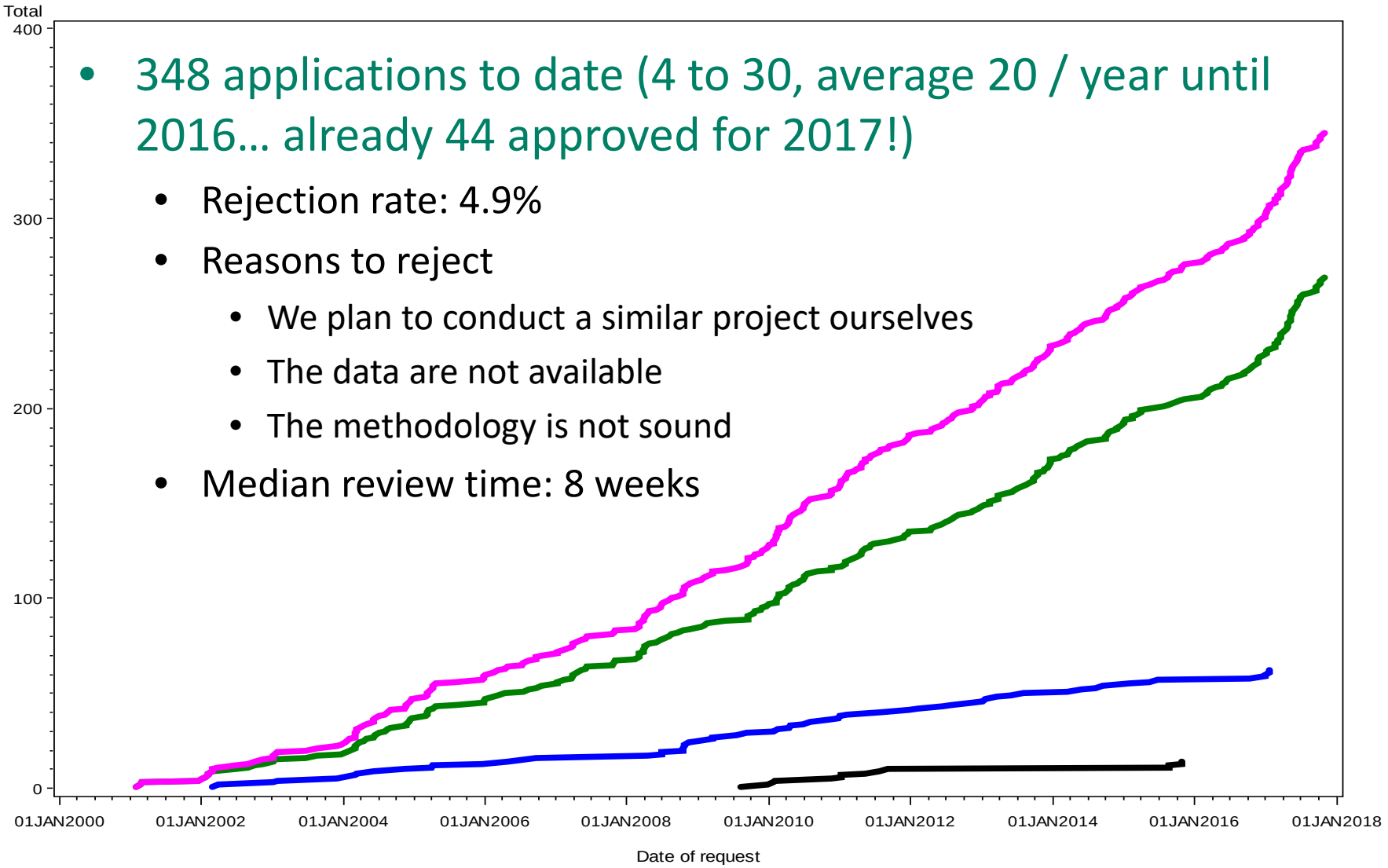
NO → **Triggers terms of use with respect to inclusion of disclaimers that work not done at EORTC and does not reflect official view of EORTC (If not)**
+ follow-up to publication
+ HQ review of the draft prior to publication

YES → **Publication follows standard path of EORTC publications (EORTC POL009)**

- Changes to the declared plan require additional approval

16 years of data sharing at EORTC

- 348 applications to date (4 to 30, average 20 / year until 2016… already 44 approved for 2017!)
  - Rejection rate: 4.9%
  - Reasons to reject
    - We plan to conduct a similar project ourselves
    - The data are not available
    - The methodology is not sound
  - Median review time: 8 weeks



What is done with the data?

- 30% were shared for meta-analyses
- 10% were shared with universities to test new statistical methods
- The rest is for secondary use of the data, alone (40%) or with biomarker results from bio-sample analyses (20%).
- None is to reproduce main study results

Publication

- 97% of the completed projects resulted in publications
- 25% of the ongoing projects already led to some publication
- We co-author 87% of the publications, reflecting collaborative work

Data Sharing at EORTC (summary)

- The process is in place and functions well
  - We are faster than many other orgnanisations
  - Fosters collaboration
  - Increases the number of publications
- Few instances of data abuse to date
- The process has a cost:
  - Logistics of reviews, administrative support needed
  - Involves of several departments (notably contracts)
  - Burden of data sharing increases
    - Sharing of more sensitive data
    - Need to de-identify (may take up to 5 days for old studies)
    - Preparation on of data documentation