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Adapting HIV cohorts to future challenges in HIV research

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Future challenges in HIV research

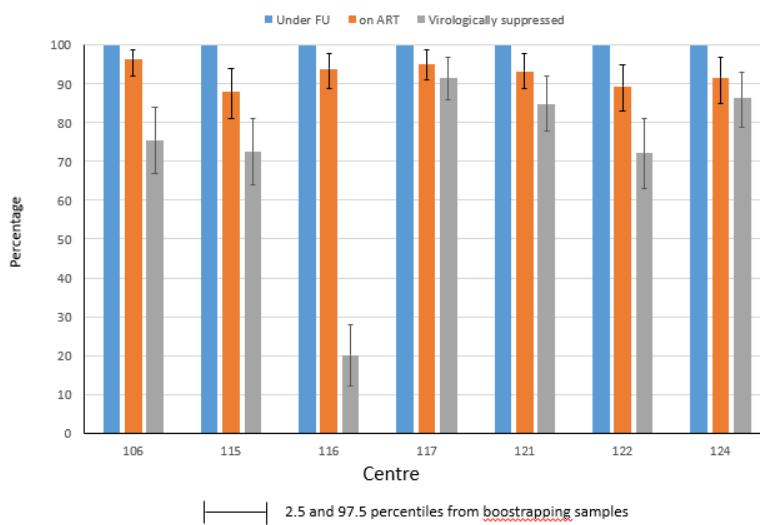
- Quality-of-care for
 - HIV
 - Co-morbidities
 - Co-infections
- Emerging health challenges
- Public health
- Biological pathways to disease – precision medicine
- Problem X

Quality-of-care

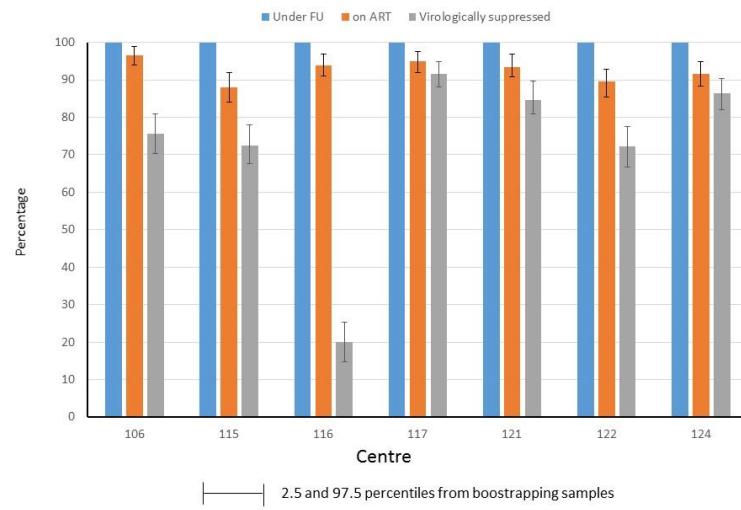
- Indicators of good care
 - Capture key features
 - e.g. ART initiation and HIV-RNA suppression rates
 - Objective and ascertainable
 - Allows for broad implementation
- Benchmark clinics
 - Optimal and suboptimal care
 - Focused training
- By definition, the more clinics in joined cohort, the better the utility of output
- ECDC, EACS, & BHIVA
 - developing an European Standards of HIV Care document

Data on 100 random patients required to establish @ the clinic level a *reliable* "right side" of the continuum of care*

B: sample size 100; 1,000 repetitions



C: sample size 250; 1,000 repetitions



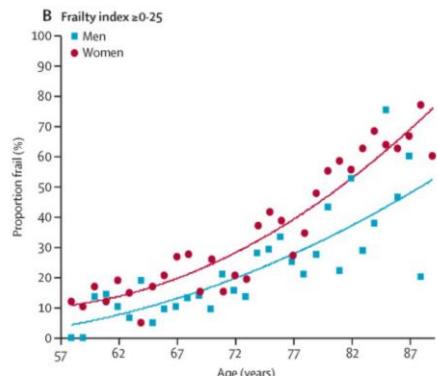
*Among those under follow-up
% on ART & % suppressed

RESPOND: Raben et al: EACS PS9/2
Friday, San Francisco Room, 10.45

Online tool tbd

Emerging health challenges

- Are we focused on the "right" health issues ?
- HIV+ population is aging
 - How do aging process interact with HIV-associated immune dysfunction ?
- New ARV's
 - New drugs – new problems !
- Long-term impact from ARV's
 - Unknown – requires rigorous endpoint ascertainment

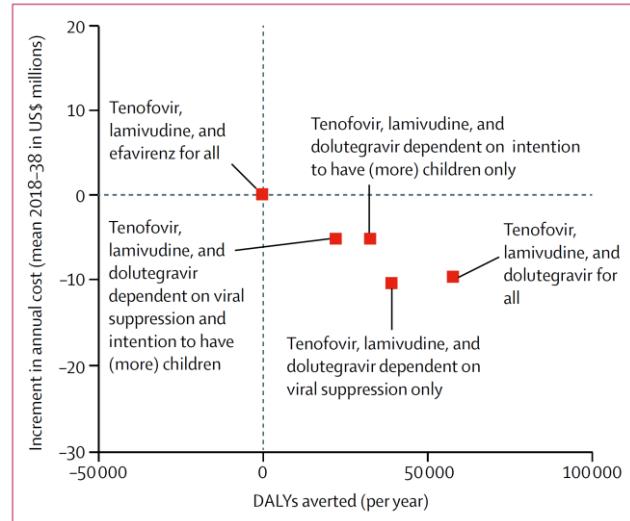


Failty by age
Hoogendoijk et al, Lancet 2019

Public health

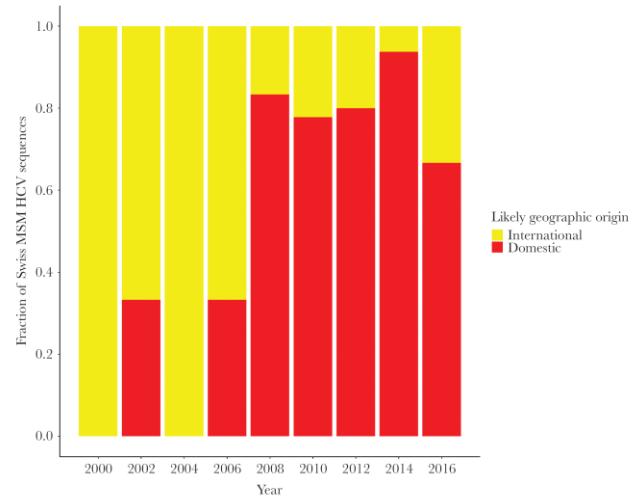
- Transmission patterns
- Transmission clusters
- Failure of preventive interventions
- Assumptions for transmission modelling

Cost eff: DTG vs EFV (+TDF/3TC)



Phillips et al, Lancet HIV 2019

Domestic vs international transmission of HCV:



Salazar-Vizcaya et al, JID 2019

PrEPaRE study: PrEP use in people newly diagnosed with HIV



- **Aim:** To assess prevalence of HIV drug resistance before ART initiation in people newly diagnosed with HIV and exposed to PrEP
- **Type of study:** observational cross-sectional study (data collected prospectively)
- **Eligibility criteria for participants:** people newly diagnosed with HIV (first visit within 3 months from the date of diagnosis) who report previous PrEP use
- **Process:** Participants will be invited to self-complete a questionnaire at the first visit if possible, and at the same time, the health care provider will fill in a CRF
- **Stage of the study:**
- CHIP sponsor; project approved by RESPOND steering committee
- 70+ clinics globally to participate; ethical processes ongoing

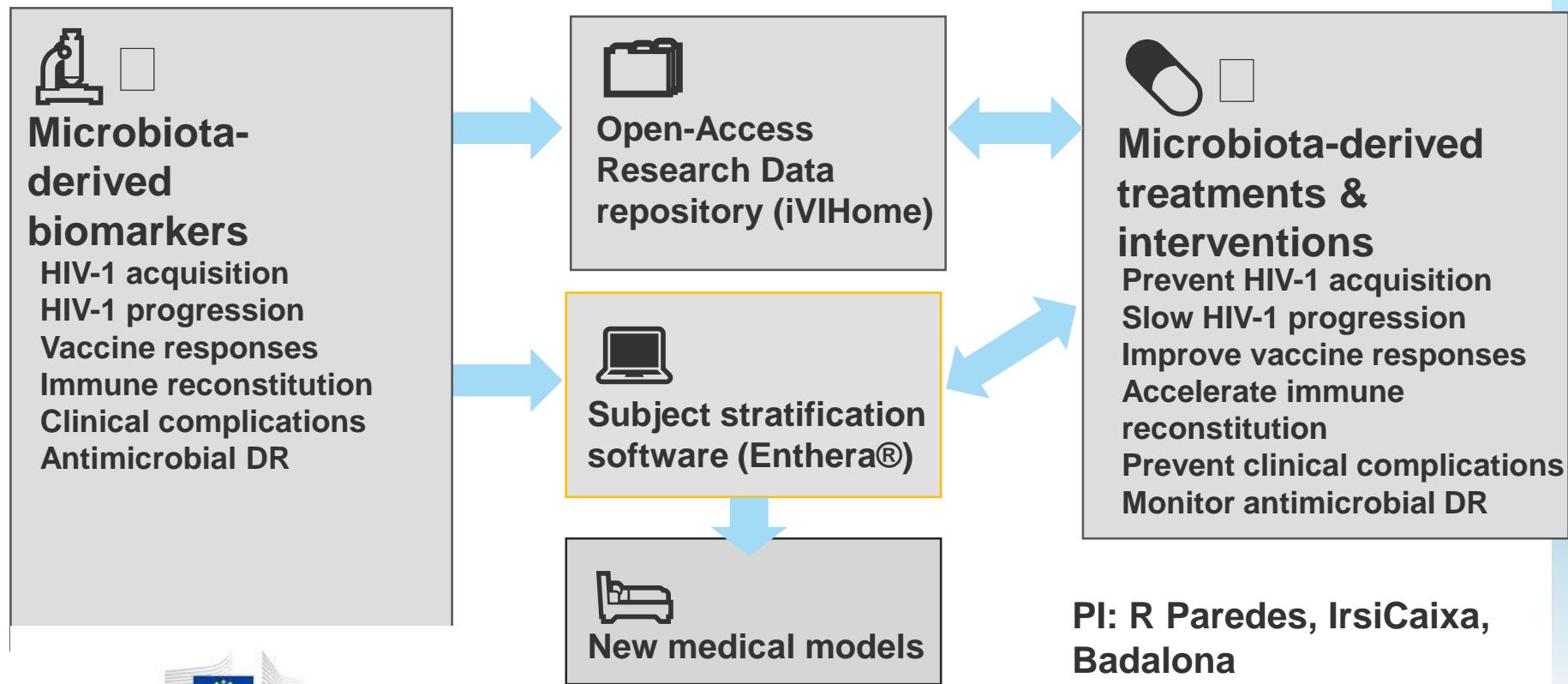


Biological pathways to disease – precision medicine

- New technologies (..omics) allows us to understand the underlying biological processes leading to poorer health outcomes
 - Come to Telenti plenary talks tomorrow morning
- Aim: to refine ability to identify persons at risk of adverse outcomes
- Requires:
 - unselected HIV cohorts,
 - comprehensive banking of relevant biological material
 - ethical permission to analyse material
 - Carefully ascertained outcomes

MISTRAL: new cohort

Microbiome-based stratification of individuals at risk of HIV-1 acquisition, chronic clinical complications, antimicrobial drug resistance, and unresponsiveness to therapeutic HIV-1 vaccination

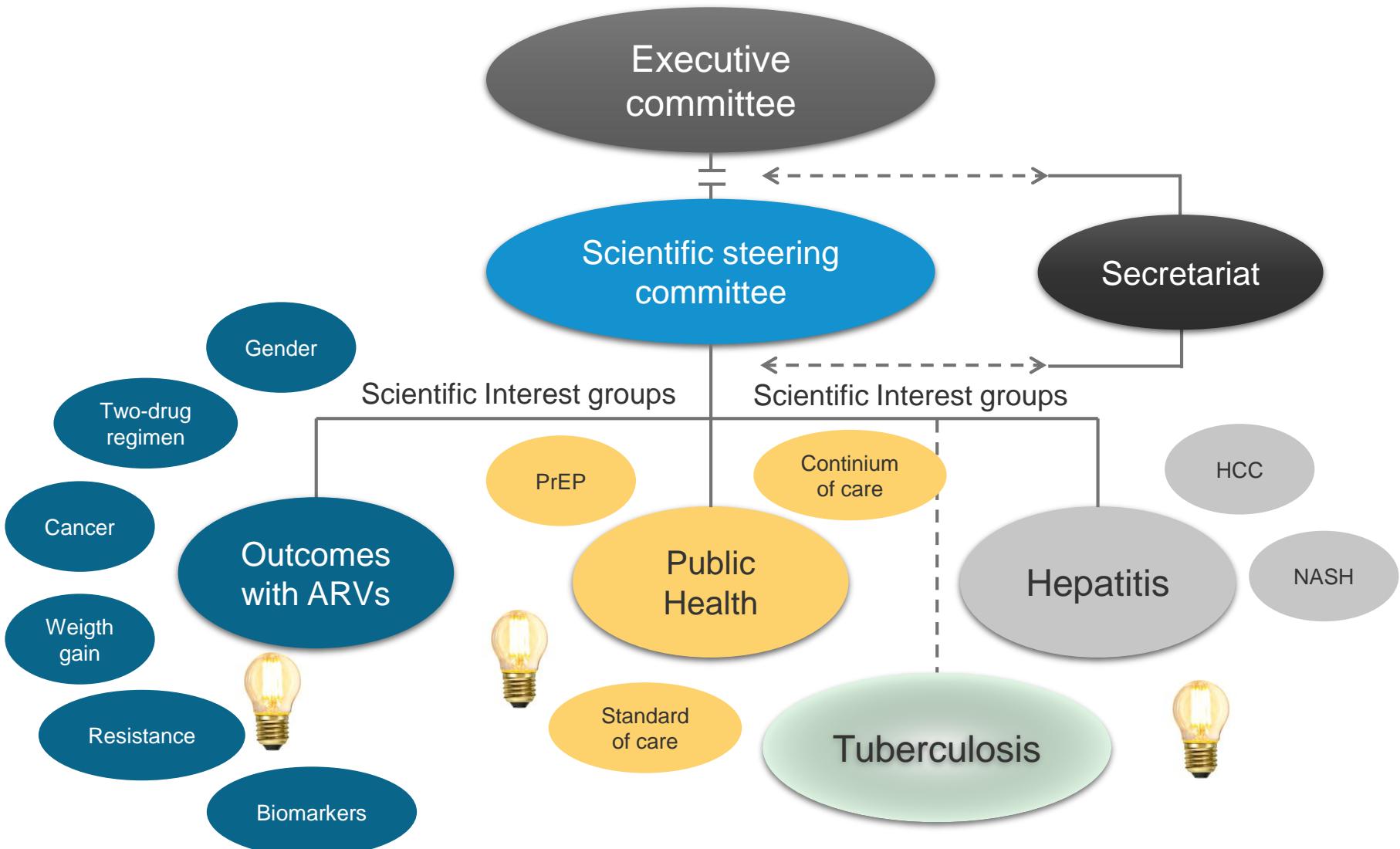


PI: R Paredes, IrsiCaixa,
Badalona
MISTRAL-HIV.eu

Problem X

- We have been surprised many times
- High likelihood this will continue
- By definition, nature of problem is presently unknown
- Ongoing cohort infrastructure allows
 - Identify emerging problem (e.g. classify causes of death)
 - Quantify problem and risk factors hereof
 - Assess impact from interventions aimed at reducing problem

RESPOND

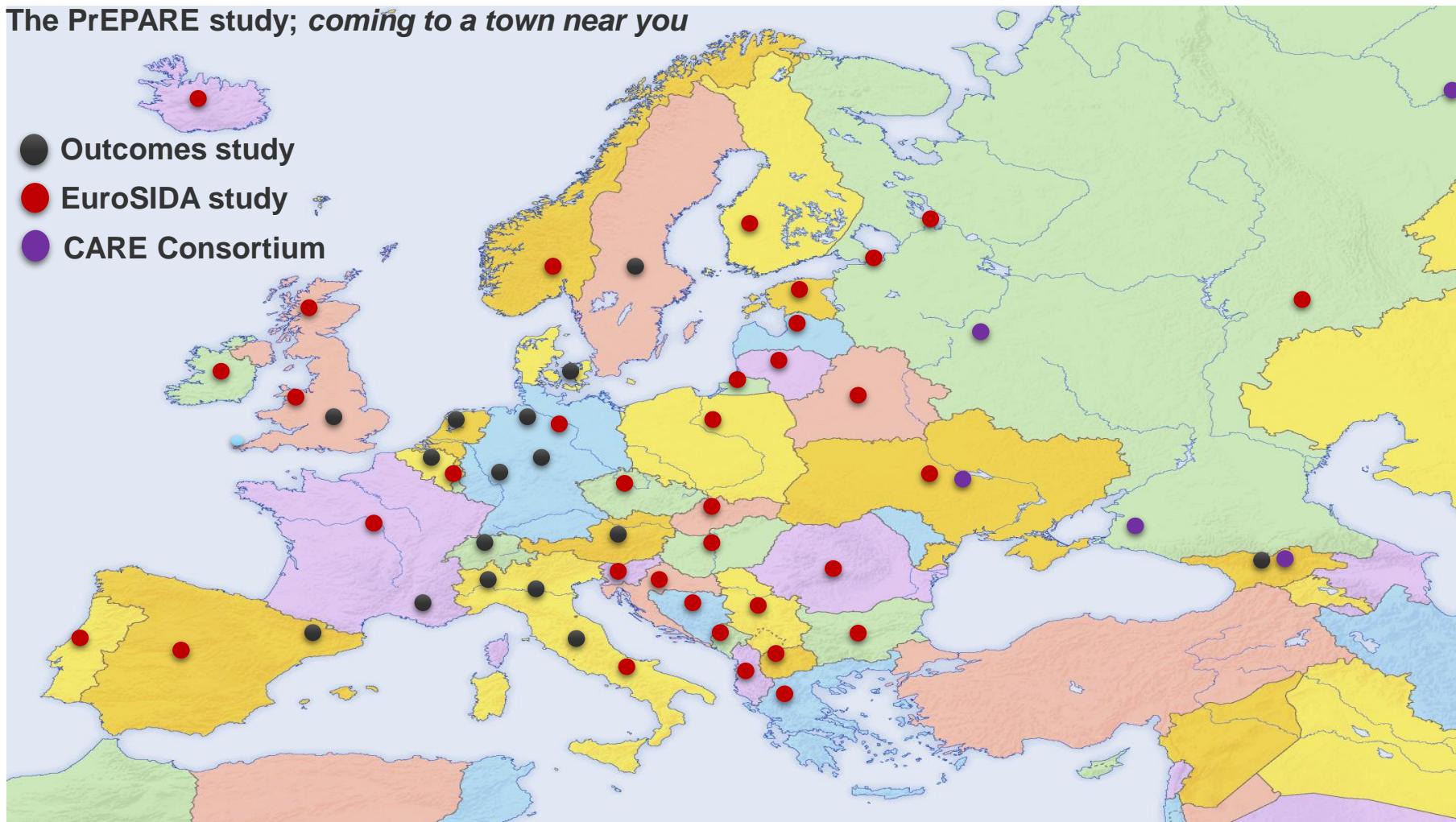


RESPOND



The PrEPARE study; coming to a town near you

- Outcomes study
- EuroSIDA study
- CARE Consortium



Neesgaard, Peters, Ryom, Mocroft, et al

Data collection tools



Two principal option for data transfer:

Database-to-database

- RESPOND electronic submission tool (**REST**)

The screenshot shows a web-based application for importing a database file. At the top, it says "Choose Project: REST RESPOND Enrolment" and "Upload databasefile - TEST.mdb". Below this is a file upload input field with the placeholder "Vælg fil" and a button "Upload new file". To the right of the input field is a link "click here to see previous errors". A red box highlights a button labeled "Export all errors to PDF". Below the file input, there is a section titled "Template errors found" with a table header "Tables". The table lists various database tables with their corresponding error messages:

- tblART: Table tblLAB_CD4 - Wrong field type in field CD4_U. Expected SMALLINT
- tblBAS: Table tblLAB_CD4 - Wrong field type in field PATIENT. Expected INTEGER

Manual data entry

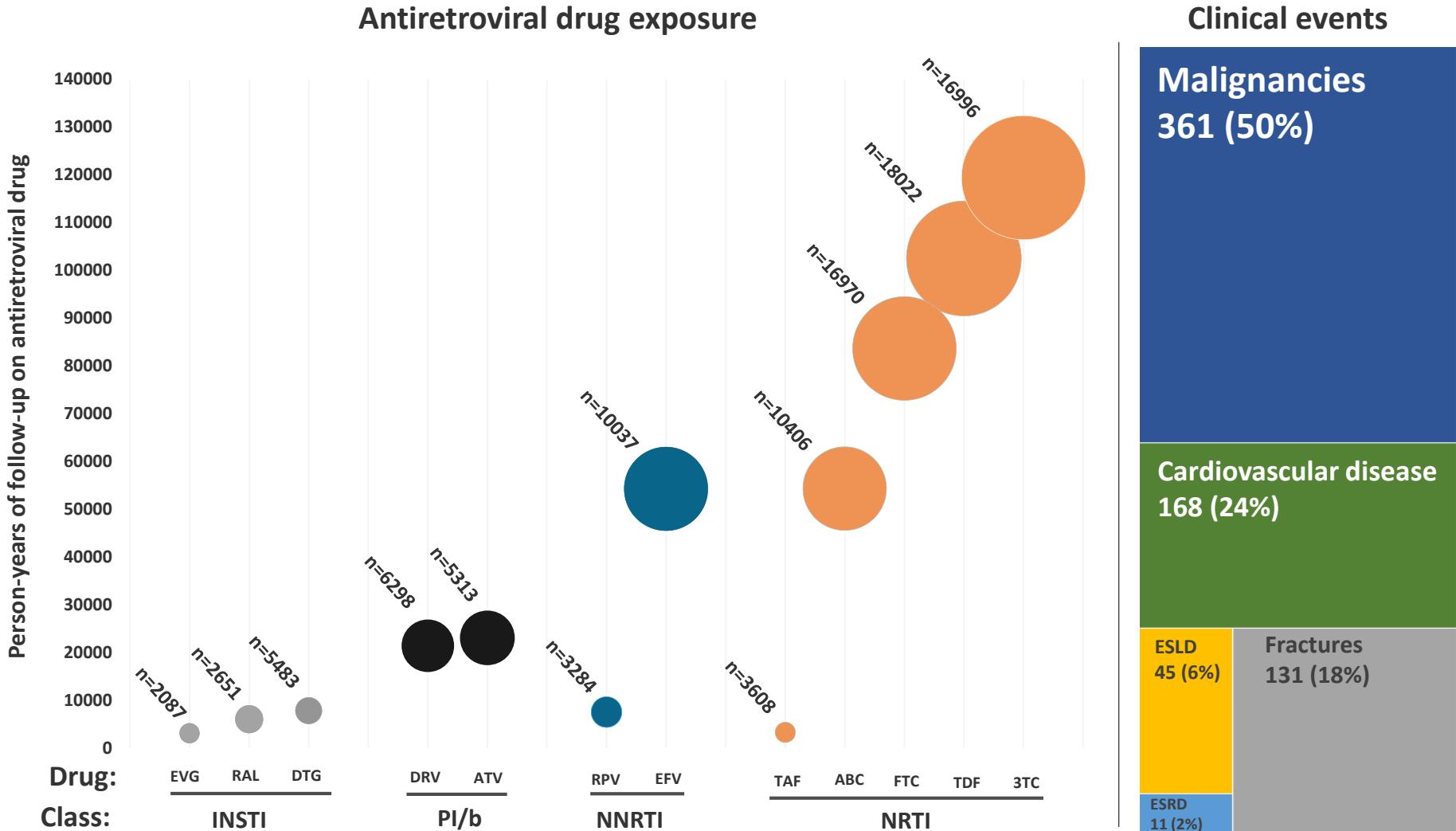
- Research Electronic Data Capture(**REDCap**)

The screenshot shows the REDCap login page. At the top, there is a logo for REDCap. Below it is a "Log In" button. Underneath the button, there are logos for several organizations:

- EuroSIDA
- hicles
- chip
Centre for Health & Infectious Disease Research
- RESPOND
- Integrate

A message below the logos reads: "Please log in with your user name and password. If you are having trouble logging in, please contact [CHIP - Centre for Health & Infectious Disease Research](#)". The main login form consists of three input fields: "Username", "Password", and "Log In". To the right of the "Log In" button is a link "Forgot your password?".

Clinical events and drug exposure



Bubble size reflects the PYFU exposed to the specific antiretroviral drug , calculated from last clinical visit, with number above each bubble indicating the number of individuals exposed.

ACKNOWLEDGEMENTS

Cohort principal investigators:

De Wit (St. Pierre, Brussels), R. Zangerle (AHICOS), M. Law (AHOD), F. Wit (ATHENA) G. Wandeler (EuroSIDA), C. Stephan (Frankfurt), N. Chkhartishvili (IDACIRC), C. Pradier (Nice HIV cohort), A. d'Arminio Monforte (ICoNA), C. Mussini (Modena), J. Casabona & J.M. Miro (PISCIS), H. Günthard (SHCS), A. Sönnnerborg (Swedish InfCare), C. Smith (Royal Free HIV cohort), A. Castagna (St. Rafael, Milano), J.C. Wasmuth (Bonn, HIV Cohort) and J.J. Vehreschild (Cologne, HIV cohort).

Cohort Coordinator, operational team members and data management:

C. Necsoi, M. Delforge (st. Pierre, Brussels), H. Appoyer, U. Dadogan, G. Leierer (AHVCOS), J. Hutchinson, R. Puhr (AHOD), P. Reiss, M. Hillebrecht, T. Rutkens, D. Bergsma (ATHENA), F. Ebeling, M. Bucht, (Frankfurt), O. Chokoshvili, E. Karkashadze (IDACIRC), E. Fontas, K. Dollet, C. Caissotti (NICE, HIV cohort), J. Fanti, A. Tavelli, A. Rodanò (ICoNA), V. Borghi (Modena), A. Bruguera, J. Reyes-Urueña, A. Montoliu (PISCIS), H. Bucher, A. Scherrer, J. Schuhmacher, A. Traytel (SHCS), V. Svedhem-Johansson, L. Mattsson, K. Alenadaf, (Swedish InfCare), F. Lampe, C. Chaloner (Royal Free, HIV cohort), A. Lazzarin, A. Poli, S. Nozza (St. Rafael, Milano), K. Mohrmann, J. Rockstroh (Bonn, HIV cohort), G. Fätkenheuer, N. Schulze, B. Frank, M. Stecher and H. Weiler (Cologne HIV cohort).

RESPOND Scientific Steering committee: J. Lundgren (co-chair), H. Günthard (Co-Chair), C. Mussini, R. Zangerle, A. Sönnnerborg, V. Vannappagari, J.C. Wasmuth, M. Law, F. Wit, R. Haubrich, H. Bucher, C. Pradier, H. Garges, C. Necsoi, G. Wandeler, C. Smith, J.J. Vehreschild, F. Rogatto, C. Stephan, N. Chkhartishvili, A. d'Arminio Monforte, A. Bruguera and A. Castagna.

RESPOND Executive committee:

Mocroft (Chair), J. Lundgren, R. Zangerle, H. Günthard, G. Wandeler, M. Law, F. Rogatto, C. Smith, V. Vannappagari and S. De Wit.

RESPOND coordination office, date management and quality assurance:

B. Neesgaard, J.F. Larsen, A. Bojesen, M.L. Jacobsen, T. Bruun, E. Hansen, D. Kristensen, T. Elsing, S. Thomsen, T. Weide and P. Iversen.

Scientific interest group moderators:

L. Ryom, A. Mocroft (Outcomes with antiretroviral treatment), L. Peters, J. Rockstroh (Hepatitis), D. Raben and J. Kowalska (Public Health), O. Kirk, A. Philips, V. Cambiano and Jens Lundgren (PrEP)

Members of the scientific interest group:

Hepatis, Public Health, Outcomes with antiretroviral treatment, PrEP, Resistance

Statisticians:

A. Mocroft and L. Greenberg

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