RESPOND Newsletter

August 2018

Dear RESPOND Study Investigators,

The RESPOND consortium is now 1.5 years of age, and it has been a very exciting first 1.5 year. A huge thank you to everyone involved, especially to the participating cohorts for all the data they have contributed.

In the spirit of continued appreciation, we would also like to thank the cohorts for the many RESPOND Event forms they have submitted, which is a most fundamental part of the RESPOND study. Approximately 90% of event forms expected at 12 months from first patients visit registered in RESPOND have been received already. THANK YOU! Please see even more achieved RESPOND milestones below.

RESPOND Milestones achieved during the first year:

- 16 cohorts were included in RESPOND in 2017
- The October 2017 enrolment, exceeded the target of including 10.000 individuals in the first year.
- The first four RESPOND scientific proposals have been developed and approved
- The first RESPOND Retreat was held in conjunction with IWHOD in March 2018. Read more about this below
- Data quality assurance programs are up and running
- Event reporting is at approximately 90 % completeness
- Three Scientific Interest Groups have been formed. Read more about the SIGs below.
- 11 meetings in SIGs and committees have been held in the first 7 months of 2018

RESPOND Scientific Interest Groups

Operating under the governance of the RESPOND Scientific Steering Committee (SSC) are the three Scientific Interest Groups (SIGs). The SIGs will generate and drive the scientific research ideas in RESPOND, and propose research concepts to the SSC. The SIGs include representatives from each cohort as well as external experts and statisticians. Depending on expertise and interest, representatives from the pharmaceutical companies funding RESPOND, will also join the SIGs. 4 Research proposals, formed in the SIGs, have already been approved in the SSC and several more are currently undergoing design and analysis.

-Outcomes with ARVs SIG:

The goal of the outcomes SIG is to study outcomes amongst persons treated with ARVs. Two projects are approved by the SSC and have started preliminary analysis. The first is studying the uptake and discontinuation of integrase inhibitors (INSTIs) and looking at both shorter and longer term reasons for discontinuation. The second is looking at immunological and virologic response to those starting an INSTI compared to a contemporary non-INSTI regimen, and will be including clinical outcomes if there is sufficient data. A third project is under development, looking at the outcomes comparing those starting a 2-drug antiretroviral regimen compared with those starting a more traditional 3 drug antiretroviral regimen.

-Public Health SIG and PrEP:

The RESPOND Public Health (PH) SIG´s first project aims to establish a better understanding of the “right hand side” of the HIV continuum of care. The goal is to develop a tool, for better estimation of the number of persons on ART and, of those the virologically suppressed. This tool will be free of charge and available online to allow countries, where such data are missing or insufficiently reported at a national level, the

opportunity to estimate their own “right hand side” of the continuum. This is essential in ensuring better quality of life for PLHIV and reducing new HIV infections.

-PrEP:
Nested in the RESPOND Public Health SIG is the PrEP module. The RESPOND and EuroSIDA network have developed a pilot project aiming at collecting information on people newly diagnosed with HIV who took PrEP prior to being diagnosed with HIV. Data collection will begin in the autumn of 2018.

-Hepatitis SIG:
The goal is to study the long-term effect of HBV and HCV therapy and other factors on the development of hepatic and extra-hepatic morbidity and mortality in HIV/viral hepatitis co-infected persons enrolled in RESPOND.
Co-infection with hepatitis B (HBV) or C (HCV) remain common and clinically important among HIV infected individuals. Although effective therapy is now available for both HBV and HCV, its use and long-term clinical outcome in a diverse real-life setting are still not well described. In the RESPOND Hepatitis Scientific Interest Group, clinicians and biostatisticians will develop and execute specific hepatitis research projects to address relevant questions in HIV/viral hepatitis co-infection research.

Submitting a proposal

All new ideas for future projects will first be presented and discussed within individual Scientific interest groups. If there is general support for a project, a short concept note is to be drafted and submitted the RESPOND Scientific Steering Committee (SSC), who will review and evaluate if there is any potential overlap with other current projects in the participating cohorts. If the SSC approves the concept, a formal proposal should be drafted and discussed in the SIG and subsequently submitted to the SCC for review and approval. Once finally approved, the project can be initiated.

The project proposal template can be found at: https://chip.dk/Studies/RESPOND/Study-documents

RESPOND Retreat

The first RESPOND Retreat was held in conjunction with the 22nd IWHOD workshop in Fuengirola Spain, on 21-22 March 2018. About 30 investigators and data managers joined the retreat for fruitful discussions on the RESPOND scientific agenda and data management. We already look forward to next year's Retreat in Athens 27-28 March 2019!

Below image is from the RESPOND Retreat in March 2018, Fuengirola, Spain

Glasgow 2018

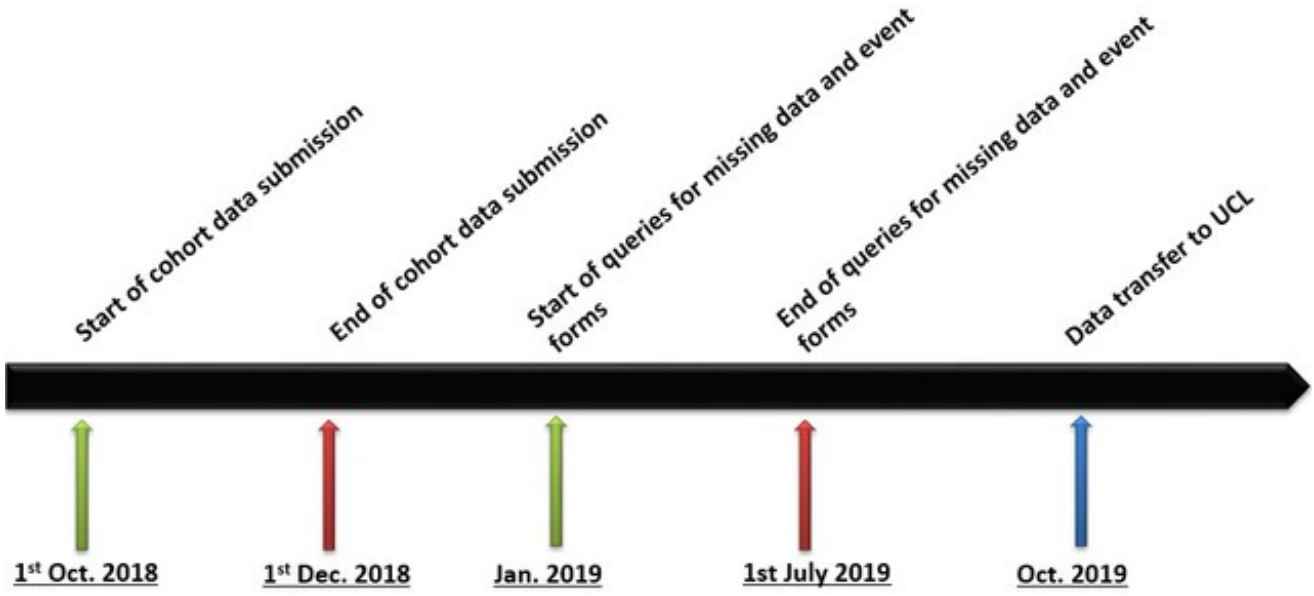
A RESPOND F2F investigator meeting has been planned for the 2018 HIV Glasgow Drug Therapy Conference. We intend to review the study progress and provide an overview of the ongoing activities aiming at increasing investigator involvement. The F2F meeting will provide an opportunity for all to meet and discuss any issues in RESPOND, especially with the data submission process.

RESPOND F2F investigator breakfast meeting on Tuesday 30th October 2018 07:00-08:00am

The meeting will take place at the conference venue, but more information will follow as the date approaches. We hope to see you there!

Reminders and notices

- If your cohort have not yet sent a brief **cohort description** to the secretariat, please do so and we will update our website
- Please make sure to continuously **check your affiliations** at https://www.chip.dk/Studies/RESPOND/Study-Group
- The REDCap **RESPOND Event form** is always open for data entry. Please continue to complete event forms for events meeting the criteria. See the MOOP HERE
- The next RESPOND follow-up and enrolment dataset will be released on **1st October 2018.** Please see timeline graphics below. For 2017 we were able to relax these deadlines, but to stick with our timelines going forward, it is absolutely essential that all cohorts submit data in a timely manner. Please contact the secretariat if you anticipate any issues with meeting the deadlines, or if you need any assistance with data submission.
- **New data items** in the coming dataset:
  -Has **pregnancy** started or completed since 1st of January 2016?
  -New Liver fibrosis evaluation tool: **ARFI**
  -Questions regarding data on **HCV therapy**, including start and stop dates and individual anti-HCV drugs



Reimbursement 2018

As we move forward with RESPOND, we will focus on data quality and the REST tool will be a valuable asset in this process. In line with this, we will be discussing further minimum data quality required for reimbursement for data submission in 2019, based on the 2017 and 2018 data submissions.

Staff and contact details

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