

RESPOND Newsletter

April 2019



Dear RESPOND Study Investigators,

We are happy to send you the second RESPOND newsletter, updating you on the progress of the consortium.

The RESPOND consortium has now been ongoing for over two years. It is fair to say, that it has been two years with a lot of work involved for all contributing partners. However, our joint venture now has a solid base, from which the scientific agendas in all three scientific interest groups are progressing and evolving.

Please note that the RESPOND scientific agendas are dynamic and offers a platform of infrastructure and data capturing tools which can be assessed by all stakeholders. Therefore, please do not hesitate to bring forth new scientific ideas and questions!

If you wish to take part in the ongoing activities in RESPOND, please contact the RESPOND secretariat.

You will find details on progression from the scientific interest groups below.

RESPOND Milestones achieved during the second year:

- Seventeen cohorts are currently involved in the RESPOND Outcomes Study.
- The October 2018 enrolment exceeded the target of including 20,000 individuals in the second year of RESPOND.
- Six scientific projects have been approved and are currently ongoing.
- The first RESPOND abstracts were presented at CROI 2019, Seattle and IWHOD 2019, Athens.
- The Second RESPOND retreat was held in conjunction with IWHOD in March 2019 (details below).
- Data quality assurance programs have been further developed and are continuously being updated.
- All three scientific interest groups are meeting regularly.
- A total of 21 RESPOND associated meetings were held in 2018 across the scientific interest groups, scientific steering- and executive committee.

RESPOND Scientific Interest Groups:

Outcomes to antiretroviral treatment (ART)

Moderators: Lene Ryom and Amanda Mocroft

Regular teleconferences and face-to-face meetings have been organized with high attendances and interest in discussing data and scientific projects. In 2018/2019 two abstracts have been developed by the group. The abstract on virologic and immunologic outcomes to integrase inhibitor treatment was presented at CROI, Seattle and the abstract on INSTI uptake and discontinuation at IWHOD, Athens. The latter will also be submitted for EACS, Basel 2019. Manuscripts are being drafted at present, and we are very excited at the prospect of the first publications.

Two additional proposals have been approved in 2018; a project examining uptake and outcomes of two-drugs ART regimens compared to three-drug regimens, and a general cohort profile describing the RESPOND consortium, involving all three scientific interest groups. In addition, three new scientific proposals were presented at the RESPOND retreat 2019 (details below).

Three new working groups were established in 2018: Definition of virologic failure in RESPOND, two-drug antiretroviral treatment and a cancer group (with additional external experts: oncologist: Mark Bower, Chelsea and Westminster Hospital, London and Peter Meidahl, Rigshospitalet, Copenhagen).

Hepatitis

Moderators: Lars Peters and Jürgen Rockstroh

The RESPOND Hepatitis SIG has ongoing research activities on both HBV and HCV. Two posters examining the influence of HCV co-infection and the impact of HCV cure on incidence of non-AIDS clinical events were presented at CROI, Seattle and the International Liver Congress in 2019. An abstract on the risk of HCV re-infection after a sustained virologic response, has been selected for oral presentation at the International AIDS Conference in Mexico City in July 2019.

In addition, analyses on hepatitis delta co-infection in HIV/HBV infected people is ongoing, with the aim of submitting an abstract to EACS, Basel 2019. The study is a joint venture also involving the Swiss HIV Cohort Study and a French HIV/HBV cohort.

Public Health

Moderators: Dorte Raben and Justyna Kowalska

Data for the continuum of care project have now been collected on more than 10.000 participants from 7 clinics in 7 countries: Poland, Georgia, Belarus, Serbia, Macedonia, Albania and Montenegro. All clinics reported data on all people living with HIV seen at their outpatient clinic for follow-up between 1 January 2017 – 31 December 2017. For the clinics in Macedonia, Albania and Montenegro – all countries with a low prevalence of HIV – data represents all diagnosed HIV - positive persons under follow-up in the country, as they are the only clinics offering treatment and care for HIV.

The aim of the project is to develop an online accessible tool, for clinics seeing people living with HIV, to help estimate the clinics continuum of care - especially for clinics in countries where this data is not nationally available.

Not all clinics can submit data electronically and different sampling techniques have been explored, i.e. all participants; born first week of each month; born 5,10,15,20,25,30 of each month; born in January etc. Using a 10% sample simulates a continuum of care very similar to the actual continuum (all persons). An abstract on the results so far, will be submitted to EACS, Basel, 2019. The next step is building the actual tool and having it piloted.

Another project in the Public Health scientific interest group is the PrEPare study. The objective is to explore whether HIV infection is likely to have occurred while the person was on PrEP or whether it is likely due to low adherence to PrEP. The study will also explore if the person has a resistant virus and monitor prevalence of HIV drug resistance before ART initiation. So far 75 sites have shown interest the study.

Submitting a proposal

All new ideas for future projects will first be presented and discussed within the scientific interest groups. If there is general support for a project, a short concept note is to be drafted and submitted to the RESPOND scientific steering committee, who will review and evaluate if there is any potential overlap with other current projects in the participating cohorts. If the scientific steering committee approves the concept, a formal proposal should be drafted and discussed in the scientific interest group and subsequently submitted to the scientific steering committee 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>

2nd Annual RESPOND Scientific Retreat

The second annual RESPOND Retreat was held in conjunction with the 23rd IWHOD workshop in Athens, Greece, on 27-28 March 2019. Investigators and data managers joined the retreat for very constructive discussions on the RESPOND scientific agenda and data management.

It was announced at the retreat, that participants from Russia and Ukraine will be included in the RESPOND Outcomes Study, from the newly formed EU sponsored Horizon 2020 project CARE (Common Action Against HIV/TB/HCV Across the Regions of Europe). CARE is a joint research venture between EU and Eastern Europe, particularly Russia, Georgia and Ukraine.

The data overview in RESPOND presented at the Retreat, was based on the first 2017 merger, as the 2018 data has not yet been finally cleaned and QA'ed. Significant improvements in QA tools and data quality from cohorts is observed in the 2018 data. Although not yet perfect, there is great optimism for the quality and completeness of data in RESPOND going forward.

Ongoing science:

List of all ongoing projects below

Status of SCC approved RESPOND Projects March 2019					
Scientific Interest Group	Status	Persons responsible	Project	Planned Initiation	Targets
RESPOND general Projects	D	Bastian Neegaard / Lauren Greenberg / Lene Ryom / Amanda Mocroft	RESPOND cohort profile	Spring 2019	Journal of epidemiology
Outcomes with ARV	W	Lauren Greenberg / Lene Ryom / Amanda Mocroft	Trends in usage of HIV Integrase inhibitors	Spring 2018	Ms for AIDS
	W	Bastian Neegaard / Lene Ryom / Amanda Mocroft	Immunological, virological and clinical outcomes of integrase inhibitor usage	Spring 2018	Ms for AIDS
	A	Lauren Greenberg / Lene Ryom / Amanda Mocroft	Two-drug regimens vs. three drug regimens	Spring 2019	TBD
Public health	D/A	Dorthe Raben / Marie Louise Jacobsen	Develop tool and methodology to assess ART coverage and virological suppression	Spring 2018	Data collection Spring/Summer 2018, Analysis and results spring 2019
	D	Valentina Cambiano / Tina Bruun	PrEP use and misuse in people newly diagnosed with HIV	Autumn 2018	Prospective enrolment of patients Autumn 2019
Hepatitis					

D=Design; A=Analysis; W=Writing; S=Submitted

New scientific proposals:

Three new scientific proposals were presented at the retreat:

1. A comparison of weight change amongst people receiving INSTIs and those receiving other contemporary ARVs (Bansi Matharu et al.),
2. RESPOND laboratory analysis concept (Petoumenos et al.),
3. Comparative efficacy of cART regimens in key populations in ARV naïve persons (Mocroft et al)

Potential new scientific areas for RESPOND:

From 2018 (last download), centres were asked about pregnancies

- Has the woman reported pregnancy since 1 January 2016? (Yes/no/unknown)
- If yes, date of first positive pregnancy test

This information will enable RESPOND to go back and collect more detailed information on women, pregnancies and outcome if required and with appropriate funding.

Currently the EuroSIDA cohort is investigating the prevalence of pregnancy in women living with HIV. The EuroSIDA study data is a first step in establishing a baseline basic epidemiology of pregnancies before the widespread introduction of INSTI and could be the base for future studies.

The possibility for adding neuropsychiatric adverse events to the RESPOND event portfolio was discussed, considering the recent reports of associations between these and INSTI use.

In addition, themed group-discussions of new scientific areas for RESPOND were conducted, and highlights from these will be presented in the coming scientific interest group meetings.

Highlights of the data managers breakout sessions:

The RESPOND electronic submission tool (REST) was discussed, and the coordinating center received valuable feedback:

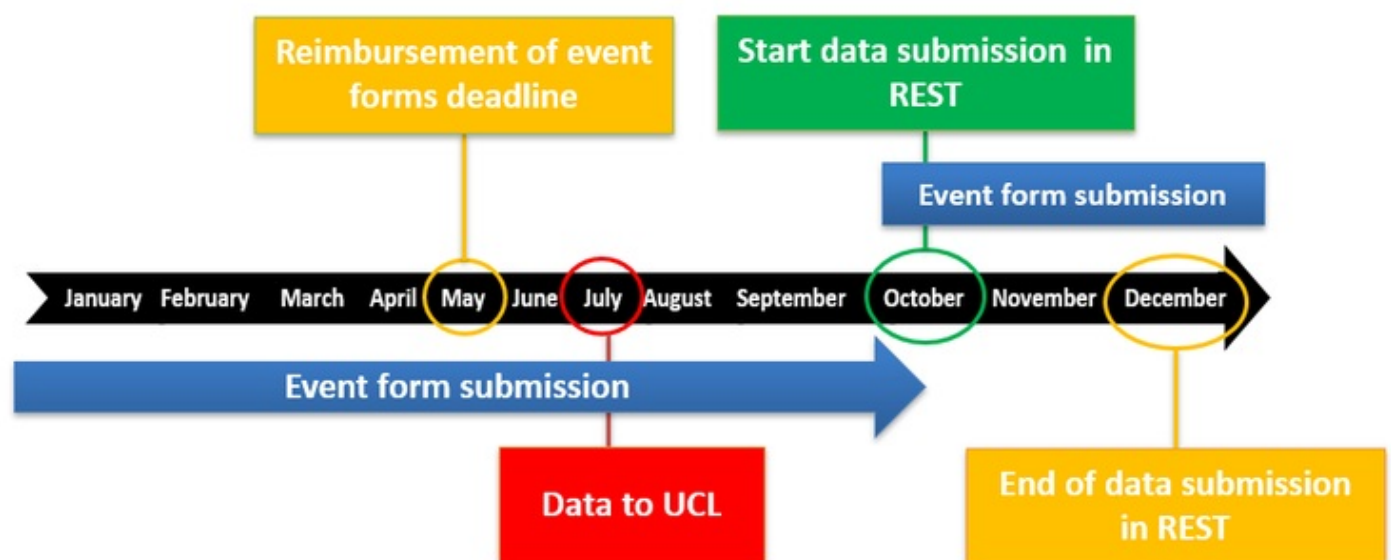
- Centers have requested the possibility to download a list containing all data errors relevant to the center, but because of regulatory issues this is not possible. Instead the coordinating center can send a center specific cumulative error list.

- Overlaps between REST checks and query mails to be optimized.

There was also a discussion on data update between datasets, the RESPOND SOP and new suggested changes to HICDEP. We will kindly ask everyone to use the discussion forum on <https://hicdep.org> to add comments and suggest changes.

Reminders and notices

- If your cohort have not yet sent a brief cohort description to the secretariat, please do so to allow for an update at the RESPOND website
- Please also make sure to continuously check your affiliations to ensure they are up-to date 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 RESPOND manual of operation (<https://chip.dk/Studies/RESPOND/Study-documents>)
- The next RESPOND follow-up and enrolment dataset will be released on 1st October 2019. Please see timelines below, 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.



17th European AIDS Conference (EAC) 6-9 November 2019, Basel

A RESPOND SSC meeting and a RESPOND PH/ PrEPare meeting are planned for EACS. More information will follow shortly.

We would like also to promote a special session at EACS 2019; a symposium celebrating the **25th anniversary of the EuroSIDA study**, on Thursday, November 7th from 16:30-17.30

Reimbursement 2019

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 requirements for reimbursement in 2020, based on the 2017 and 2018 data submissions.

The 2019 reimbursement, covering the second data merger October-December 2018, will increase in two ways. First, the budget allows for the reimbursement of 20,000 persons in 2018 compared to 10,000 persons in 2017 and secondly, it has been decided to reimburse both enrolment and follow-up forms with 20 euros, an increase of 2 euros

per person for the enrolment form.

Staff and contact details

Contact information:

The RESPOND Secretariat

Tel: +45 35 45 57 57

e-mail: respond.rigshospitalet@regionh.dk

Website: <https://www.chip.dk/Studies/RESPOND>

Fax: +45 35 45 57 58

Coordinating Center Staff:

Project Management

Jakob Friis Larsen jakob.friis.larsen@regionh.dk

Public Health: Marie Louise

Jakobsen marie.louise.jakobsen@regionh.dk

PrEPaRe: Tina Bruun Tina.Bruun.01@regionh.dk

Scientific Staff

Lars Peters Lars.Peters@regionh.dk

Lene Ryom lene.ryom.nielsen@regionh.dk

Bastian Neesgaard bastian.neesgaard@regionh.dk

IT and Data Management

Erik Viuff Hansen erik.viuff.hansen@regionh.dk

Thomas Willum

Elsing thomas.willum.elsing@regionh.dk

Management Coordination

Dorthe Raben dorthe.raben@regionh.dk

Statistical Center

Amanda Mocroft a.mocroft@ucl.ac.uk

Lauren Greenberg l.greenberg@ucl.ac.uk



RESPOND Coordinating Centre. Rigshospitalet, CHIP, Department of Infectious Diseases, Section 2100, Finsencentret. Blegdamsvej 9, DK-2100 Copenhagen Ø, Denmark.

Tel: +45 35 45 57 57. Fax: +45 35 45 57 58. E-mail: respond.rigshospitalet@regionh.dk

Web: www.regionh.dk www.chip.dk

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