Section: Contact Information

First Name : **Cecile**
Last Name : **Ronckers**
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Section: Project Requirements and Description

Group: Requirements to submit AOI

A comprehensive review of previously published data has been completed. : **Yes**

The specific aims are clear and focused. : **Yes**

The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator. : **Yes**

The investigator agrees to develop an initial draft of the concept proposal within 6 weeks of approval of the AOI and to finalize the concept proposal within 6 months. : **Yes**

Project Title : **International pooled analysis of breast cancer risk after treatment for CAYA cancer - evidence to support further tailoring of the IGHG Breast Cancer Surveillance Guideline**

Planned research population (eligibility criteria) :
Multiple International Cohort and Case-Control Studies with sufficient numbers of cases and adequate follow-up methodology for breast cancer.
Including SCT and Wilms- only cohorts for specific research questions.

These include the Original and Expanded cohorts of CCSS (purpose of this AOI)

Proposed specific aims :
Childhood cancer cohorts
- Risk of BC after high-abdominal RT
- Risk of BC after TBI
- Risk of BC after low-dose (<10 Gy) chest-directed radiotherapy
- Risk of BC after combined chest RT, pelvic radiation exposure and/or chemotherapy

optional:
- Risk of BC after RT exposure specific to timing of RT relative to menarcheal age

For now the Research Questions are driven by questions identified in the IGHG development process.
In the future, once the collaboration and the data set have been established, this can be a resource for other Research Questions to be analyzed as part of the Consortium.

Also, Flora van Leeuwen will lead on a second task within this Work Package, involving young Hodgkin Lymphoma survivors, since the IGHG guideline covers older AYA survivors as well.

Will the project require non-CCSS funding to complete? : **Yes**
If yes, what would be the anticipated source(s) and timeline(s) for securing funding? : **Dutch Cancer Society**

deadline twice a year
upcoming deadline 1st week of December

Group: Does this project require contact of CCSS study subjects for:

Additional self-reported information : **No**
Biological samples : **No**
Medical record data : **No**
If yes to any of the above, please briefly describe. :

Group: What CCSS Working Group(s) would likely be involved? (Check all that apply)

Second Malignancy : **Primary**
Chronic Disease :
Psychology / Neuropsychology :
Genetics :
Cancer Control :
Epidemiology / Biostatistics : **Secondary**

Section: Outcomes or Correlative Factors

Late mortality :
Second Malignancy : **Primary**

Group: Health Behaviors

Tobacco :
Alcohol :
Physical activity :
Medical screening :
Other : **Correlative Factors**

If other, please specify : **reproductive factors**

Group: Psychosocial

Insurance :
Marriage :
Education :
Employment :
Other :
If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech :
Hormonal systems : **Correlative Factors**
Heart and vascular :
Respiratory : **Secondary**
Digestive :
Surgical procedures :
Brain and nervous system :
Other :
If other, please specify :

Group: Medications

Describe medications :

Group: Psychologic/Quality of Life

BSI-18 :
SF-36 :
CCSS-NCQ :
PTS :
PTG :
Other :
If other, please specify :

Group: Other

Pregnancy and offspring : **Correlative Factors**
Family history : **Correlative Factors**
Chronic conditions (CTCAE v3) :
Health status :

Group: Demographic

Age : **Correlative Factors**
Race :
Sex :
Other :

If other, please specify :

Group: Cancer treatment

Chemotherapy : **Correlative Factors**

Radiation therapy : **Correlative Factors**

Surgery : **Correlative Factors**

Section: Anticipated Sources of Statistical Support

CCSS Statistical Center : **Yes**

Local institutional statistician : **Yes**

If local, please provide the name(s) and contact information of the statistician(s) to be involved. :

<to be determined>

Local PI's (Ronckers/van Leeuwen/Kremer) and post-doc (Jop Teepen) are experienced in dealing with large datasets and analyzing time-to-event and radiation dose response data

Current idea is to work with two experienced SMN statisticians in tandem, to provide oversight in developing the detailed analysis plan + to check on final analyses. We are currently discussing collaboration with Chaya Moskowitz (MSKCC) and Michael Hauptmann (NKI/AvL).

We will update Dr Armstrong and Dr Neglia once intention to collaborate has been confirmed. Anticipated early November.

Will this project utilize CCSS biologic samples? : **No**

If yes, which of the following? :

If other, please explain :

Section: Other General Comments

Other General Comments :

- This proposal has been discussed with the CCSS Subsequent Breast Cancer Working Group in the Oct 26 call (Chair J Neglia)

- Potential overlap with the Turcotte et al proposal for pooling international data on main effects of chemotherapy and SMN risk has been discussed with Dr Robison. More conversations on how to proceed jointly are anticipated once the DCOG LATER Board has reviewed the Turcotte et al proposal (anticipated in November)

We look forward to working jointly on these and other important SMN Research Questions.