

TARPSWG MEETING MINUTES

San Diego, March 27th 2019, SSO

Attendants: Samuel Aguiar, Sanjay P Bagaria, Dan G. Blazer III, Savtaj Brar, Katherine Broughton, Dario Callegaro, Ferdinando Cananzi, Kenneth Cardona, Peter Chong, Andrea Covelli, Jeremiah Deneve, Nicolas Devaud, Sinziana Dumitra, Mark Fairwhethear, Jeffrey Farma, Marco Fiore, Samuel Ford, Rebecca Gladly, Neha Goel, Jonathan Greer, Valerie Grignol, Alessandro Gronchi, David Gyorki, Trevor Hamilton, Fabian Johnston, Brian E. Kadera, John Kane, Christina Lynn Roland, John Lyons, Andrea MacNeill, Gary Mann, John Mullinax, Carolyne Nessim, Deanna Ng, Eran Nizri, Shreyaskumar Patel, Elisabetta Pennacchioli, Venu G Pillarisetty, Martha Quinn, Chandrajit Raut, Emily Ryon, Rupen Shah, Jason Sicklick, Dirk Strauss, Lorena Suarez Kelly, Suren Subramaniam, Carol Swallow, William Tseng, Winan Van Houdt, Jiping Wang, Francis Zih

Apologizes: Toru Akiyama, Marc Bemelmans, Peter Hohenberger, Charles Gillham, Shintaro Iwata, Leandro Nikisch, Marko Novak, Vittorio Quagliuolo, Eberhard Stoeckle, Raza Sayyed, Sergio Valeri

Welcome and Introduction by Dr. Gronchi

RESAR Update (Dr. Marco Fiore)

- 29 active sites
- 27 sites recruiting
- 4 sites waiting for REB approval
- 13 centers interested
- If all join we will be 47 centers

- 23 European, 16 North American, 3 Canadian, 6 Asian and 1 Australian
 - 865 patients in the registry
 - By the end of 2019: 1000 patients expected

- Milan awaiting for institutional grant for the Registry to be centralized in Milan
 - The group agrees to centralize data.
 - Security protected web format would be provided
 - Milan has a person in IT working on that

[** Update on April 5th: Financial institutional grant by Fondazione IRCCS Istituto Nazionale dei Tumori has been approved for the support of RESAR project including centralization and data monitoring for a 5 years period. Centers participating to RESAR will be soon approached for further details about the operationals**]

- Inclusion of persistent/residual primary RPS in the RESAR database
 - The group agrees to include these patients
 - Discussion on the definition of the data points to be included in this new section (see document attached)
 - Regarding the size of the tumour: it will be included the maximum tumor diameter based on imaging, if available
 - Include also peri-operative treatments at time of first surgery

- *Definition of Residual disease:* evidence of persistent residual disease at the first post-operative scan obtained within 6 months after the initial surgery
- The group discussed the possibility of a new registry about non-operated RPS patients. It has been agreed to wait next future before activating such a new project.

ACTION: Marco Fiore will circulate the proposed dataset for persistent RPS to the group final approval

- Inclusion of data about second malignancies in RESAR dataset
 - Data points for this new sheet were discussed
 - Decision to include information about synchronous second malignancies in order to put into a context RPS management
 - Previous/Subsequent cancers will be recorded in order to catch up possible hypothesis generating information
 - Previous cancers will be recorded in order to catch up information about previous radiation causing radiation induced sarcoma (presently not recorded in RESAR)

ACTION: At the current time we will focus on synchronous cancers + previous RT for other cancers

RESAR Pragmatic RCTs (Dr. David Gyorki)

- Registry based RCT Pragmatic trials
 - Prospective RCT that uses a clinical registry for one or several major functions for trial conduct and outcomes reporting
 - Rapid recruitment
 - Lower cost
 - Each site runs their own randomization
 - Multiple identical minor RCTs and final study is analysed as a meta-analysis
 - Requires grant funding to ensure adequate data quality
 - May require >1 sponsor for the trial
 - It will be allowed to accrue patients into more than one trial at the same time
 - Randomisation of distinct subsets of patients to current SOC without strong supportive evidence
 - E.g. Neo-adjuvant RT for WDLPS
 - E.g. Investigations of patterns of care with regards to imaging surveillance and optimal imaging interval (***)We currently do not collect this data in the RESAR registry to answer this question)

- E.g. ERAS vs. SOC (***)We currently do not collect this data in the RESAR registry to answer this question)

ACTION: To ensure that at time of any RCT activation, we should have to potentially adapt or add new data points to be able to run the trial

First RESAR Study Morbidity Surgical Complexity Score (Dr. Mark Fairweather) (TARPSWG #1901)

- ACS risk calculator exists but not really relevant for RPS
- Aim of this study would be to predict post-op morbidity in RPS and to use it to better inform patients preoperatively
- No extra data will be asked that are not presently included in RESAR
- The choice of data to be analyzed will be guided by previous TARPSWG manuscript about postop morbidity in primary RPS (MacNeill)
- Consider to add preoperative creatinine and albumin
- Scores to be assigned at single factors and/or resected organs should be better evaluated; in alternative this could be done after MVA.
- Based on the numbers of centers interested, 27% will need a DTA and roughly 800 patients will be accrued
- Goal is to submit an Abstract to SSO in October 2019

ACTION The following deadlines schedule is approved:

- Mid April: final deadline to *opt in* for TARPSWG 1901
- End of May: data to be centralized in Milan.
- End of June: data cleaning / data queries
- September: statistical report
- October: abstract submission for SSO 2020
- *Please, contact Marco Fiore asap if your center requires a specific data transfer agreement.*

Pathology Guidelines (Dr. Gronchi):

- An update on WHO Classification of Soft tissue and bone sarcoma will be held in Lyon in May 2019
- Proposal to promote a consensus among pathologists for standard sampling and report RPS specimens
- Relevant items to agree upon in a comprehensive pathologic report: evaluation of response to neo-adjuvant treatments, evaluation of surgical margins, evaluation of organ invasion, tumor Grade
- Ideally this effort may be finalized within the occasion of next Sarcoma ESMO conference to be held in Milan in February 2020

- Proposal to ask Elizabeth Demicco and Bibi Purgina (two pathologists members of TARPSWG) if they would be interested in leading the project of synoptic report for RPS

ACTION: TARPSWG members are encouraged to ask their local pathologists if they are interested in this project of creating a standard pathology report, and in case communicate to Dr. Gronchi before May 2019.

STREXIT (Dr. Carol Swallow):

- STREXIT: Patients operated at 10 centers participating to STRASS and treated out of the STRASS protocol within the study time frame has been analyzed
- Baseline characteristics of the STREXIT group were comparable to the STRASS group
- STREXIT vs. STRASS tumours were smaller, fewer grade 3, multifocality was the same, tumour rupture rare and the same
- More WDLPS in STRASS than STREXIT
- Less pre-op radiation therapy in STREXIT
- R2 resection was very low in STRASS
- Use of preoperative radiation therapy in STREXIT was ranging between 4-74% in different centers
- Use of preoperative chemotherapy ranged between 0-26% in different centers

REC Update (Dr. Carolyn Nessim):

- Resume of succeeded and completed projects:
 - *TARPSWG 1700* - Schwanomma (Sam Ford, manuscript ready to be submitted)
 - *TARPSWG 1701* - Recurrent Sarcoma Nomogram (Chan Raut, published)
 - *TARPSWG 1702* - Whipple for RPS (Will Tseng, published)
 - *TARPSWG 1805* - STREXIT (Carol Swallow, SSO2019, CTOS 2019)
- Resume of ongoing projects
 - *TARPSWG 1801* - Neo-adjuvant chemotherapy project (Dr. Will Tseng): very preliminary data, still open to join for other centers, please contact the PI. Goal would be to submit an abstract for CTOS 2019 (deadline in June).
 - *TARPSWG 1802* - left pancreatectomy project (Dr. Sanjay Bagaria): only preliminary data available, data cleaning still ongoing. Possible update in occasion of next CTOS 2019
 - *TARPSWG 1803* - Myxoid liposarcoma (Dr. Carolyn Nessim): still possible to join, contact the PI. Goal would be to submit an abstract for CTOS 2019

- *TARPSWG 1804* - Mesenteric sarcoma project (Dr. Sam Ford) very few patients available, please consider to join the study even if your center has any patients, and directly contact the PI *TARPSWG*
- *TARPSWG 1808* - Postoperative morbidity in recurrent RPS (Lahat, Nessim): further analysis ongoing. Goal to submit an abstract for CTOS 2019.
- *TARPSWG 1809* - Post-relapse outcome after 2nd recurrence of RPS (Dr. Rebecca Gladdy, van Houdt, Fiore) statistical report available, manuscript to be prepared.
- New projects Presented
 - *TARPSWG 1807* – Pelvic Sarcomas (Pelvisarc) (Dr. Fiore, Dr. Dumitra) dataset to be collected will be circulate soon together with invitation to participate
- General recommendation for future project to strictly adopt a common standardized dictionary for variables, in order to make it simpler both data cleaning and repeated data entry in multiple projects (e.g. M=0, F=1 etc). Ideally ALL future studies should mutuate from the exiting dataset of RESAR the format of all the available variables, and establish accordingly any further specific new variable
- General agreement to consider the use of “TARPSWG” acronym within the title of all the manuscript from common projects of the Group.
- **ACTION:**
 - Members are invited to use the existing RESAR Excel datasheet as a baseline template whenever they will propose a new project
 - The REC will include in its Protocol Proposal Template that TARPSWG must be mentioned in the title of the Manuscript

STRASS 2 (Dr. Winan vanHoudt):

- STRASS 2 will be a RCT led by EORTC investigating neoadjuvant chemotherapy in high grade RPS.
- Inclusion Criteria:
 - DDLPS
 - LMS
 - FNCLCC grade 3, included grade 2 if no necrosis on biopsy but obvious necrosis on imaging and high risk as well as based on Cinsarc score
 - Must be resectable at presentation
- Total 7 years with 250 patients accrued over 5 years
- Surgery with or without preoperative chemotherapy (Adriamycin + Ifosfamide for DDLPS and Adriamycin + Dacarbazine for LMS)
- Primary Endpoint is DFS
- Secondary Exploratory
 - Endpoints on PET-CT, MRI etc.
 - Translational research projects will be done once funding is secured

- Patients not entered on the Trial should be entered into the RESAR database in order to put results into context
- 2 interim analyses to allow potential need to expand the cohort to ensure that the study will not be underpowered
- No Radiation therapy will be considered in the protocol unless STRASS will be positive (results awaited for ASCO 2019).

The meeting was adjourned at 6 p.m.

Next Semi-Annual Meeting will be held in Tokyo in occasion on CTOS 2019: save the date for **Wednesday November 13th, 2019, 2-6 pm, Hotel Hilton Tokyo, Ran room on the 3rd floor.**

Slides presentations referred to the discussed agenda may be retrieved at <https://wp.me/P8yhDh-cj>