ICVR May 31, Iceland

1. **PAD Discussion:** Survey country registries about current use of which level of variables from the ICVR recommended variables for PAD (Christian)

   PAD Variation project: Vascunet will start collecting basic PAD data, other sources available (such as insurance data), project can start when Vascunet data available Christian, Danny

   Attendees indicated that almost all registries have enough data for a practice variation among countries analysis. CLI vs claudication, endo vs open. Next step: develop a method for aggregate data sharing with Cornell to avoid new European GDPR privacy rules. Ask each registry what they collect. Aggregate data at center level unless number of patients too small, then combine into "small centers"

2. **Global amputation trial**: Christian presented the recent Vascunet Amputation study. Martin discussed the World Federation of Vascular Surgery project on global PAD guidelines. WFVS is considering monitoring of amputation rates globally. They want to select regions that can provide population based data on all amputations including trauma. Variation data can be used to incent funding for amputation prevention measures in countries with high amputation rates.

3. **AAA volume-outcome**, data presented by Kevin. The first paper will focus on the overall volume-outcome for EVAR, Open, intact and ruptured aneurysms. Then, additional papers on % EVAR in a center, effect of increasing EVAR over time on overall mortality of rupture. Very interesting volume outcome analysis.
   a. Primary paper: Kevin, Jon, Adam, Sal authors,
   b. Send invite to all centers to get authors for other 2 studies above

4. **Carotid volume outcome**, data presented by Jialin. No center volume effect was found, except in cranial nerve injury rate, which was higher in higher volume centers. Need to do subgroup analysis by country since definitions may differ. Future projects: add data 2014-2017 and consider effect of time from index symptom to CEA on outcome, and add CAS data. Start process for each registry to submit 2014-2017 data, and then decide when collected whether it can be sent to Cornell or arrange remote access for server in Europe.

5. **rAAA Device Evaluation**: Danica emphasized the strategic priority of FDA to use RWE, and 50 device decisions in last year were based on RWE. IMDRF has approved the ICVR rAAA project as the first pilot project to meet their requirements for device decision based on RWE. The next steps are to finalize protocol, approach companies as well as FDA and other regulators with proposal for their approval. So in US, if company wishes to use this process to remove labeling limitation, they would bring pre-market group in to approve plan going forward. Scott Williams has contacts at Notified Body TUV, for the next step after FDA approval. Detailed study protocol was described by Art Sedrakyan but it is likely to change based on FDA input. First plan to ask FDA for preliminary approval of in hospital mortality as the primary outcome measure, this could come during a call before ICVR submits a formal pre-submission request for FDA review. (Adam, Kevin)

6. **Send letter to EC** requesting clarification of regulations around transfer of data to US if fully de-identified. This is an important question in order to continue to be able to do centralized data analysis Other options are distributed analysis and then combine the results.

7. **Need authors** for AAA projects and QI project (proposal for next meeting)

8. **New ideas for future projects**
   -Dissection with malperfusion
   -TEVAR for aneurysm ? neurologic CX vs size/extent TAA
   -Create project proposal and define data needed for subsequent data collection
   -Carotid patch type and outcome
   -Popliteal aneurysms, Martin doing Vascunet project next year
   -Outcome of branch grafts in BEVAR, FEVAR
   -Groin wound infection
   -Quality improvement project: ASA statin at DC? How many registries collect it?
   Need project leaders for any of above that could be started.

9. **For Next Meeting agenda**
   TEVAR specific project (Christina), QI project DC meds, look at PAD pts, Brigitta
10. **The next meeting will be on Wednesday during the Veith-meeting on Wednesday, November14. The next spring-meeting will be on 2019, May 22-23 in Bordeoux, France.**