The Corelab Tasks and Responsibilities

Ulrich Beschorner
Bad Krozingen / Germany
Disclosure

Speaker name:
Ulrich Beschorner

I have the following potential conflicts of interest to report:

- Consulting:
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s): Medical Director CoreLab Bad Krozingen

- I do not have any potential conflict of interest
Why do we need a corelab?

Physician’s interpretation of vascular imaging can be biased by many factors:

- Individual experience
- Individual preferences
- Awareness of symptoms
- Awareness of treatment options
- and many more…
Why do we need a corelab?

Example: Male 54 y patient, Severe Claudication right leg
ABI: 0.6
Duplex: 80% distal SFA stenosis

Patient is included in a DEB trial
Angio:
High grade stenosis in distal
SFA by visual estimation
Why do we need a corelab?
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For clinical trials we need:

- Unbiased interpretation
- Independent interpretation
- Exact interpretation
- Measurable results
Is a corelab’s interpretation better than a physician?

- The physician’s interpretation is much better for the individual patient
- The corelab shall capture unbiased values for a clinical trial

Different objectives!
Imaging modalities in vascular medicine that might require corelab support:

Quantitative Vascular Analysis (QVA)
Imaging modalities in vascular medicine that might require corelab support:

Vascular Ultrasound
Imaging modalities in vascular medicine that might require corelab support:

Stent X-ray
Imaging modalities in vascular medicine that might require corelab support:

CT / MR - Angio
Imaging modalities in vascular medicine that might require corelab support:

OCT, IVUS
How do I get corelab suitable imaging?

Different objectives!

A really good duplex / angio for clinical needs might be nondiagnostic for the corelab
How do I get corelab suitable imaging?

Complete

Comprehensible

Measurable
Example: duplex ultrasound for a SFA stent trial
Complete?

Please show the vessel with color duplex so we can determine where the measurement was taken.
Comprehensible?

Please adapt color duplex scale so blood flow and turbulences can be detected properly.
Comprehensible?

This is obviously too low for this vessel...
Measurable?

Please optimize Doppler angle insonation (≤ 60°)
Measurable?

Please ensure cursor alignment is parallel to vessel wall.
Measurable?

Please adapt velocity scale
This seems to be quite good?
For each measurement please document:
Where did you take it?
When did you take it?
What trial?
What subject number?
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