General Bio-Tool Research Ethics and Legal Queries

Ethics Approval:

Depending on what is being done with the bio-tools, a clinical study protocol and/or ethics approval will be necessary for each WP8 trial that uses a bio-tool.

Generally speaking:

- if the use of tools remains in the form of transferring data or lab samples, or even usability by a user (e.g. can they handle the tool) then normal research ethics approval processes will apply. This would involve details like participant recruitment, consent procedures, and a DPIA.

- if the use of the tools includes biological data – e.g. monitoring vitals, sampling from a person, or supporting diagnosis/intervention decisions, potentially even biobanks -- then a clinical study protocol approval – and potentially safety board -- will be necessary in addition to the research ethics approval. Any trial that involves biological data needs to design a clinical study protocol, often in line with GCP standards. This protocol would need to be submitted somewhere (e.g., hospital ethics board, local ethics board, EU) as part of STAMINA's ethics approval. Central ethics boards are possible, but this would need ethical approval in site countries. This can take time, probably a few months. These require detailed plans for representative samples, population size, unique informed consents and data management plans, incidental finding plans, etc.

Questions to answer still regarding approvals:

- Who would submit the clinical study protocol and where will it be submitted? To which boards?
- For each country, how far in advance do these need to be submitted (ethics or clinical)?

Warning from our AB about triggering an Ethics Check:
According to one of our ethics AB members who reviews this regularly for the EC, we would almost certainly trigger an ethics check mid-project were we to decide to follow through with human trials of the bio-tools (e.g. use them within STAMINA actively on human subjects). Based on AB experience, this would be very time consuming and risk stalling project momentum. The ethics check is likely because during the GA phase, the project stated it was not doing medical research on humans or genetic sampling, just lab-based data/samples that did not raise human research subject/clinical ethics issues.

Questions to help determine which route to take:

- What is being tested in the trials: the usability of the tool, the tool's ability to correctly diagnose, or whether it can provide helpful data to STAMINA? Something else?
- Do we need to collect new samples from subjects to achieve the objectives of STAMINA? Can this be done in another way (e.g. biobanks), synthesised data?
- What is gained/lost in not using these tools on human subjects during STAMINA?

- What of this is required in the GA?