Subtitles and transcriptions
Subtitles and transcriptions are available for selected materials for purpose of helping users understand the contents of the educational sessions.
Uncertain words have been indicated with ?? before and after the part.
Parts that could not be understood at all have been indicated as [Audio Not Clear].

Every effort has been made to faithfully reproduce the audio of the sessions as recorded. However, no responsibility is accepted for mistakes or omissions. ESO does not endorse any opinions expressed in the presentations.

Discussion and Q+A

Prof Pruneri: Thank you. Now we should have 10 minutes or so for the discussion or these last talks. Maybe Jeroen if you want to take the lead for the discussion.

Prof van der Laak: Yes, Sure. So, I think we had a very nice session and diverse topics. And I think the regulation, of course, is an important topic, as was just indicated by Marcial. So, let's see if we have any questions from the audience. So, if you have any questions, please put them in the chat. I would have a question for you Emanuela to start discussion. So, you said you do anonymization of the images before they are transmitted, can you explain a bit how this works? Because if you anonymize the images then you will not be able to know which patient you're dealing with. Or did I misunderstand?

Dr Bonoldi: Repeat, please. What was it? The question was about the patient?

Prof van der Laak: Yeah. What I understood was that you anonymized the images before they are transmitted, but how can you do this if this is a direct patient care? If you anonymize the images, then you will not be able to get result back to the patient. So how is this possible?

Dr Bonoldi: Okay. Anonymization was requested, was specifically requested for the project by the ethical committee. The only two, the slides are anonymized by the software and by the server which collects the images. The slides are bar coded, and the only two partners who knows, obviously, the names of the patients, the clinical information, the history of the lesions are the ones of the two institutions who both make the primary diagnosis and receive the patient. These are the only two. A consensus format is required to be signed from the patient to allow this. That is what we do.

Prof van der Laak: Yeah. Okay. I understand. Yes.

Prof Pruneri: Well, it's a sort of pseudo-anonymization. So, it's...okay.

Prof van der Laak: That's not fully anonymized, yes. So, how was it with, especially, I think, Giancarlo, for you, if you work with Kyrgyzstan but maybe also for Emanuela, at some point you sought to rely on telepathology and you're doing remote consultations or teaching. I think you should also be able then to rely on your equipment, right? You should know there is a stable internet connection. I could imagine with, especially Kyrgyzstan, but also maybe even within Italy, this may

be a challenge, or maybe not a challenge but at least some kind of a risk. Have you thought about this? Is this a problem?

Prof Pruneri: Yes definitely. It is a problem, you know, what you're mentioning is one of the most important flows in the infrastructure of digital pathology. My opinion? We have fantastic software, fantastic ways of capturing the images. The problem is that we have a very unstable clusters for the infrastructural informatic clusters in our institution, especially in a hospital, this is quite, you know, bad in my opinion. Let me just tell you that it's another story, but with regard to the storage of the images from stemming from next generation sequencing, we just invested in our institution more than 500,000 euros this year, just in order to build the infrastructure. So again, I think that this absolutely one of the most important hurdles that limit the implementation of digital pathology, at least in Italy, I don't know in other countries.

Prof van der Laak: Is that the same for you, Emanuela? Do you see there is a challenge?

Dr Bonoldi: Of course, we have this problem. Just for example, we had the opportunity to try to perform this project because there was a firm who gave us free server as a repository of 1000 slides. So, let us imagine. But at the same time, it may be that, if we can succeed in make understand that even preserving 50 years in Lombardia, we have to maintain, we have to preserve for 50 years blocks and slides. So, maybe it's a big effort, isn't it?

Prof van der Laak: Yes, it is.

Dr Bonoldi: So, it's just a matter of approach, I think it's a matter of approach, but it's difficult to make it understand.

Prof van der Laak: Yeah. And I think everyone is struggling to some extent with the same challenges in that sense, I think. So, there is a question here in the chat, it's not directed to anyone in particular, but I think it's, because it's on AI, I could imagine it's mostly for Marcial. Some research will say that you can use federated learning to develop AI by collecting patient data from different medical centres, compliant with GDPR. What is the advantage of that? And how does it work? Could you inform us about using federated learning in digital pathology? Marcial, do you have any experience with federated learning?

Dr Garcia Rojo: Yeah. It's a quite interesting approach because instead of having a single very large repository, it's kind of, distributing the efforts between different resources in different institutions. And there it may be also a common economically, maybe more affordable. So, from the technical point of view, it makes some complexity in terms of trying to harmonise into a standardised some data formats and measuring standards and so on. But yeah, from the computing point of view, it's, let's say, an intermediate way of going to a cloud, which is something that our public health institutions sometimes are not able to understand that is really needed. And instead of doing all the efforts locally, you can distribute these efforts between different institutions. So, I think it's a very interesting approach. And probably in some research projects, like the Big Picture, that is being led by Jeroen, probably this approach can also be very interesting for research also.

Prof van der Laak: So Marcial, also to address a question that I had in your talk. So, if it's about certification, do you think it's the role of mainly the companies, primarily the companies, or should we also as researchers, users, pathologists, be active in that field? Or should we just leave it up to the commercial parties and after get the certifications they require?

Dr Garcia Rojo: Well, in fact, the new regulation in the European Union makes a good opportunity for pathologists, for clinicians, to participate in this process because clinical validation studies are really needed, and they need to demonstrate by these clinical studies that these tools, can be a scanner, or can be on artificial intelligence algorithms, are really working in the sense that companies are mentioning. Because until now, it was enough with demonstration that the system is working as the manufacturer is saying. But now it is not enough, you have to demonstrate by these clinical studies. And I cannot see any kind of clinical studies with the participation of pathologist and the rest of medical specialists.

Prof van der Laak: I think we have a question in the chat that relates to this, and that it's also relates a bit to the discussion we had in the previous session. So, there is a new regulation in the EU which is called the IVDR. And the question is, how does the IVDR impact for further development of digital pathology solutions and its adoption in clinical practise? In the last session, we also talked a bit about lab developed tests, and yeah, we had a bit of sentiment that if you can validate it as your own lab, be it digital pathology or AI, that would be sufficient. I'm not an expert but as far as I understand, with the IVDR, you're not allowed to do this. If there is any kind of certified product, you have to go for the certified product and you're not allowed anymore to have lab developed tests, which makes things maybe a bit more complicated. And maybe for all of you, yeah, how do you feel about this? Will it make things much more complicated, more expensive maybe?

Dr Garcia Rojo: The thing is that we as pathologists, are used to these kinds of problems. Remember when we were not able to use antibodies because they were for research purposes only, but we were using them in clinical practise work because we had no other choice. This is the idea, the idea is regulation is needed, but in clinical practise you have to move on. And what we will do probably is we will validate these new algorithms, even if they are not under this regulation, because they have made significant changes. For instance, these systems are able to learn from new cases, they are not closed systems, they are open systems. We really want to see them in clinical practise, but probably it's going to be very hard for them to follow these new regulations. At the end, what we will do, we will make our own clinical studies locally and we will make use of them if they really work. That's my opinion.

Prof Pruneri: Yes, may I just add a very brief comment? I think that I'm absolutely agreeing with you. I think that it will not be a problem related to the software of the instruments, because they will be certified and that's it. They will probably cost more than now, but this is the only downside. The problem will be the procedures, because with regard to a project like that of Emanuela, of course, you have to validate all the procedures because they should be sort of laboratory-developed tests. And so, you had to validate the results, probably, you know, now I'm just guessing, but probably by doing a head-to-head analysis using traditional pathology and digital pathology. But it will be a cost at least in terms of time, this is for sure.

Prof van der Laak: Emanuela, anything to add?

Dr Bonoldi: Yeah, I agree. I think that a real strong commitment is needed, a real one. It can't be a local, well, to experiment. Experimentation is kind of curiosity, is the answer to a personal or team curiosity. But then to translate from experiment to real life, ordinary life, ordinary work, you need rules, you need procedures, you need reliable data. And that depends upon the strengths of the government. It's really a political matter, for me, it's a political matter.

Prof Pruneri: Yes, in this regard, may I just ask a question to Marcial, I mean. Don't take me too trivial, but do we have an idea of the reimbursement of the system? Because reimbursement will be an issue in the next years, I think. So, what can you... how is the weight of multi-disciplinary discussion in digital pathology of the case?

Dr Garcia Rojo: Well, regarding reimbursement, for instance, this is an interesting issue that I remember from the first papers of [Audio Not Clear] regarding the way of trying to understand that by having a more objective diagnosis, you can save lives, you can save money. Because, for instance, you can avoid errors in the way patients are going to be selected. And you make a very good point with HER2 in Kirghizistan, and this is a good point in which, for instance, in HER2, interpretation, we can save a lot of money. We can do it very well, avoiding treatment patient incorrectly. And this is the major, I think, point where you can save money. There are other approaches, like the possibility of working in network, avoiding transportation of cases, transportation of patients and cases, and so on. Avoiding buying microscopes and so on. But this is nothing to do with the cost that it means not treating well, our patients.

Prof van der Laak: Okay, thanks. I think we have to come to a conclusion. I think it's great to see all these promises of digital pathology and AI in pathology, which seem to cover a very wide area. We have many, many challenges that digital pathology may help with. So, with that, I would like to thank all the speakers, of course, Giancarlo, being my co-chair and speaker, double role this afternoon. I think we had two great sessions. So, I would like to conclude and give the floor to, I think Catarina, probably.

Prof Pruneri: Thank you so much.