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Are digital workflow and AI implementation under regulation?

Dr Rojo: This presentation is about the use of regulations and the need of regulation in digital pathology workflow, and the implementations of artificial intelligence in pathology. First, I would like to thank organizers, the European School of Oncology, and the European Society of Pathology, and, of course, Professor Catarina Eloy, for their kind invitation. My name is Marcial Garcia Rojo. I'm the Head of the Pathology Department at the Hospital Universitario Puerta del Mar in Cádiz, in Spain. The agenda that we will follow in this presentation, is first some figures on the change that we have now with digital pathology, with digital imaging now in pathology, and also, why we need these regulations in digital pathology and artificial intelligence implementations. And also, we will cover some very specific regulations in these fields. And some of the recent applications that have been already described on the use of artificial intelligence in pathology. And finally, some conclusions. Pathology for many years has been the most valuable source of information because we have very well organized specimens, very well structured data. Not only final diagnosis, but also descriptions, gross/microscopic diagnosis, comments, information about techniques. We are also very good in coding, mainly topography and morphology. And this means that we are generating a very large amount of data. For instance, in Spain, with almost 50 million inhabitants, we have about 5 million pathology reports every year, and 10 million histology slides in one year, only in public hospitals, with human resources of about 1,200 surgical pathologists. These figures has been calculated using the figures that we have in Andalusia. In Andalusia, we are 8.5 million inhabitants. In public hospitals, we are generating almost 2 million slides every year. And there is quite a large amount of them, for instance, dedicated to Dermatopathology, which is one of the main fields in our specialty. It means about 25% of all the surgical pathology activity in many of our hospitals. This means, of course, a quite complicated technical issue of archiving, of a storage, of all this amount of information. Our approach is to have a temporary high-performance storage system with about 250,000 slides that this high-performance system will only have an annual growth of about 5%. But the technical issue is to have this permanent large capacity of storage which will be significantly increasing every year. As we said, it will be increasing in almost 2 million slides every year, which means a growth of about 5PB every year. If we consider that average size of one single slide is about 3GB. Of course, it can be also improved with better compression systems. Considering that storage costs are low, and are going lower every year, we have calculated that we will need in 10 years about €12 million to manage all this amount of storage that is needed in digital pathology. There are many, not only images, there

are many systems that can be affected by this digital transformation in pathology, E-learning, workflow management, back system, data mining, and so on. I don't think that everything is mature enough. In pathology, we can be probably in level three or level two in some cases, or level three of maturity of all these systems, considering the top level that could be level five, but there is an increase in implementation of these systems every year. And probably we will reach this level five in a few years-time. So, it is clear that we need to regulate, not only digital pathology, but also all the problems that are related to the computational work, to the computational use of all this large amount of information that need to be integrated with all the systems and is, what we call, computational pathology. And this is very related to artificial intelligence and that's why we need also to regulate in this sense because pathology is changing. It's not only the use of a specific instrument, like an optical microscope. We are using scanners, computers, new software, and all these need to be clarified in order to make secure use of all these digital pathology systems. One of the questions that most colleagues usually make is, but really do we need to digitize everything, all the slides, and the answer is yes. We need to simplify workflows because having double workflows, one analogic and one digital, is too complicated. And also, because we must consider that we have some advantages that we have already seen. In digital pathology, we need to offer the best option to all the patients. It's difficult to select which patients will be favored with the best technology. So, the idea is to digitize everything because to allow, for instance, not to deteriorate with the time, the staining of the slides, or the danger that they may get lost, we can avoid that. Also, because these patients can benefit from a more objective quantification in biomarkers, for instance. It makes easier that exchange communication, telepathology and so on. And what has come in now, artificial intelligence, it's only possible if we can use deep learning is because we already have digitized the slides. And also, to avoid digital gap in this specialty, we need to start from research, from training residents and so on. And so that we can be ready to use all these systems in clinical practice. And essentially because it will be an essential part of the medicine of the future. And also, we must consider that there will be a continuous increase in demands of a storage, increasing image resolution. Soon, we will be working with hyperspectral images. There will be the need, for instance, in cytology, of having Z-stack or multiple planes, all this needs a continuous improvement process. So, it is clear, in the workflow, we must integrate very well, all these quantitative analyses, all these digital slides in the clinical practice, but now also, we need to integrate artificial intelligence, and that's why we need some specific regulations in this sense, you know. And this is one of the answers to the questions. Do we need to keep everything, and for how long? If we want to have artificial intelligence systems very well-trained, we need to keep benign disease, normal tissues, and it's impossible right now to select which slides I'm going to keep, and which digital slides I'm going to delete. If we want to have prospective long-term cohort studies, deleting normal or deleting specific pathologies' images, because we have not enough storage, that is really a challenge. Right now, we are not able to predict what will be the future applications of digital pathology, or of artificial intelligence. Probably, we will need some morphological, molecular and genetic data, in the future, that we are not able to predict now. And that's why the criteria that we select now to delete data, they will not accommodate the needs that we will have in the future. And ensure data storage needs, we can make some calculations now, but probably, in the future, the demands will be increasing quite a lot. And as you know, current deep learning classifiers demand a large amount of data to have very well-trained systems. The good news is that digital slides are very large images and they contained already a large amount of data, and this also made that these systems are working very well in our field. But remember, it's not only about images, we also need to train the system for genetic data. For instance, there are already some algorithms, deep learning algorithms that are helping us to understand next generation sequencing data, in all the steps, from sample preparations, to variant filtering, or annotation, and this makes the study of mutations in cancer, for instance, much easier. Some specific regulations in clinical practice we must consider, personal data protection, patients' right and obligation, electronical medical record. Not only European regulations in this sense, but also, national regulations. Of course, the new regulations, European and American regulations, on in vitro diagnosis, cybersecurity, electronic signature, digital administration, is now very well known in the society. And, of course, the new regulations on artificial intelligence. And also, in research and training, we need some specific

regulations on biomedical research laws, and biomedical research, ethical principles. Pathology is part of the electronic health-record and in this sense, some of the elements, like the pathology information system, including traceability system. The digital slide management system, not only the viewers but also all the management software that is needed for the local or central repositories. Teleconsultation, telepathology and remote diagnosis, image analysis, artificial intelligence tools. All these are elements that need specific regulations considering that they belong to the electronic health-records. This is needed because patients are already demanding access to personal health data and images. For instance, in order to regulate this, we also need to accomplish all these needs in every single element that we have in the different pathology information systems. And also, because we need to promote the international standards, IHE, HL7, DICOM, SNOMED CT, which is the only possibility to really integrate all these elements that we have in pathology with the rest of the electronic health-records. There is some specific regulations on artificial intelligence that also applies to pathology. For instance, in the United States, CLIA. They consider that the algorithms that are developed are okay when you do this validation on implementation basis, but when you make some changes in these algorithms, probably, until now, as we have regulations right now, we will need to make a new validation for a new implementation or an update of the system. The American Medical Association is quite worried about patient privacy and confidentiality, but there are many questions arising. For instance, how much safety? How much validation is needed in an artificial intelligence system to be applied to clinical practice? Will this result in unemployment? This is a possible social impact that we need to analyze in artificial intelligence, and in case of any danger or any failure of the system, to whom the responsibility falls, these also need to be defined. And, of course, there is a very important balance between the ethical guidance that we need in the development of the system, but also, we need to avoid important details... delays, sorry, in the development of artificial intelligence. Industry self-regulation is not enough, and the role of the College of American Pathology, European Society of Pathology and so on, is very important in what is needed, that is mainly a peer regulation. In this sense there are some Allen, Allen for instance. Some papers, like these from Allen, in which they anticipate what is needed for new regulations in artificial intelligence. In this case, in pathology, some flexibility, some adaptation, probably, there are regulations, and the way we regulate until now can be changed. Also, the participation of not only some specific experts, but it's more important to have multi-disciplinary councils in order to achieve more objective conclusions, and to avoid this uncertainty and information deficits that we have now in artificial intelligence. So, it's also a good opportunity for to understand the role of enterprise liability because now we have humans and now we have machines, but any of them can make an error. And this is important to define, what is the responsibility. And that's why some new concepts like enterprise liability can play a role. The current scenarios that we have in the implementation of artificial intelligence is pathology. It is clear that these are very specific tools, and in no ways they are not going to replace any human, any physician, in the near future. They are mainly designed to improve efficiency in very repetitive tasks. There is a recent survey that outlines that 71% of pathologies indicate that artificial intelligence tools can increase their diagnosis efficiency. The College of American Pathologists insists that we need rigorous validations and studies between clinical use. And of course, there are some tools already approved for in vitro diagnosis, and some commercial solutions that are available in the market. But also, we need to improve the regulations, in the sense of the market approval. For instance, as some of the possible applications in this paper from Cheng et al. with the collaboration of Liron Pantanowitz, is that we can use artificial intelligence, for instance, to select area of interest, to reject bad-quality images, to pre-order some specific stains, to do a screening and diagnosis. For instance, to select in large number of cases which of them has a squamous cell carcinoma. It can be done on the background or the pathologists can launch these specific tools, and also you can avoid very repetitive tasks like counting mitoses, counting biomarkers, and so on. And at the end, we will have additional information that we can include also in our reports. How it is done, because we need a very good integration between the pathology information system and the digital pathology system. The question is, in order to develop and in order to implement these artificial intelligence tools in the digital pathology system, do we need to connect to a Cloud system, an external system in which there will be the possibility of storing very large amount of data, and to

perform very high demanding, maybe in order to train this system, we need very high computing resources and this can be in Cloud? Both the storage and these computing resources, or this can be implemented in local servers? This author first described very well, the different issues and regulations that we need to consider in both models, going to an external Cloud system or having these local on-premises services. And in this sense, we must remember that if we are talking about artificial intelligence, if we are talking about managing a large amount of data, we must consider other specialty tools. In conclusion, digital pathology affects general workflow in pathology departments and needs new regulation. There is an unprecedented large amount of data that is needed now and the efficient use of this amount of data needs new regulations, and also some normalization and standardization. Artificial intelligence demands new regulation scenarios, also in pathology. Of course, there are some commercial artificial products already available that have been cleared in the market, but they are only focused on very specific problems. So, validation is also encouraged with artificial intelligence is implemented in clinical practice. And finally, artificial intelligence implementation should consider not only pathology data, but the integration of data from multiple medical specialties. So, thank you so much for your attention.