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MACHINE MD:
Law and Ethics of Health-Related AI Case Study 3:

Digital Twins

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This report was drafted by Caroline Mercer and Sophie Nunnelley in collaboration with the participants of the Machine MD: Law and Ethics Case Study on Digital Twins.

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Law and Ethics Case Studies in Health-Related AI

The CIHR-funded *Machine MD: How Should We Regulate AI in Health Care?* project is led by Colleen M Flood (Law, University of Ottawa), Teresa Scassa (Law, University of Ottawa), Catherine Régis (Law, Université de Montréal) and Anna Goldenberg (Senior Scientist, SickKids). The project is dedicated to investigating the legal and ethical issues raised by artificial intelligence (AI) in health care and to developing recommendations for their optimal governance.

Part of the Machine MD team's work includes examining real AI technologies, the practical issues they raise, and their current treatment in Canadian and foreign law. This approach moves beyond abstract concerns into concrete realities, helping to inform law reform with a better understanding of real-world applications. The goal is to support beneficial AI technology innovation, while minimizing associated risks through appropriate legal governance.

In keeping with this aim, the Machine MD team has partnered with CIFAR to host a series of online case study events. Each event assembles an interdisciplinary group of experts in AI, law, ethics, policy, and medicine to discuss the regulatory issues raised by a specific AI technology. This report summarizes the findings of the third case study in the series. The two previous events addressed the OR Black Box (March 4, 2022) and the Suicide Artificial Intelligence Prediction Heuristic (March 11, 2022).[1]

[1] A previous AI & Health Care: A Fusion of Law & Science collaboration also included similar case study analysis. See: *AI & Health Care: A Fusion of Law & Science — An Introduction to the Issues*, drafted by Michael Da Silva in collaboration with the participants of the AI & Society workshop for AI & Health Care: A Fusion of Law & Science (Toronto: CIFAR, 2021), online: <https://cifar.ca/wp-content/uploads/2021/03/210218-ai-and-health-care-law-and-science-v8-AODA.pdf >; a companion report addressed the regulation of medical devices with AI. See: *AI & Health Care: A Fusion of Law & Science — Regulation of Medical Devices with AI,* drafted by Michael Da Silva in collaboration with the participants of the second AI & Society workshop for AI & Health Care: A Fusion of Law & Science (Toronto: CIFAR, 2021), online: <https://cifar.ca/wp-content/uploads/2021/05/AI-Healthcare-A-Fusion-of-Law-Science-II.pdf>.

Case Study #3: Digital Twins

1 April 2022 (Online via Zoom)

The term "digital twin" refers to the emerging possibility of using a combination of technologies, including artificial intelligence, predictive analytics, augmented / virtual reality, and the Internet of Things, to create virtual replicas of physical entities including human beings and human organs.[2] The concept, borrowed from engineering and industrial design, would allow simulated courses of action to be tested on digital twins before being carried out in the "real world." For example, in healthcare, the technology could allow clinicians to better prepare for surgeries, experiment with alternative courses of treatment, and predict future medical issues.[3] For instance, a clinician could use a digital simulation of a patient's heart to compare treatment options and predict likely outcomes and disease progression.

The idea of using digital twins for personalized healthcare is gaining traction quickly. It has been described as one of the "ten most strategic emerging concepts for the coming years" and is attracting significant funding and research.[4] However there are also legal and ethical concerns associated with the technology relating, for instance, to privacy, algorithmic bias, the possibility of over diagnosis, and the risk that unequal access to digital twins could worsen existing inequalities in healthcare. This event examined the potential benefits and challenges associated with digital twins through a presentation by one of its developers, commentaries by legal scholars, and breakout sessions where participants sought to better understand — and help resolve — problems.

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[2] The term "Internet of Things" is used to describe automated networks of connected devices, including smartphones, wearables, smart thermostats, lights, and refrigerators (see Matt Burgess, "What is the Internet of Things? WIRED explains", (16 February 2018) *Wired*, online: <https://www.wired.co.uk/article/internet-of-things-what-is-explained-iot>.

[3] Matthias Braun, "Represent me: please! Towards an ethics of digital twins in medicine" (2021) 47 J Med Ethics 394.

[4] Robert Saracco, "Digital twins: Advantages and issues of a powerful emerging technology" (14 June 2018), *IEEE Future Directions* (blog), online: <https://cmte.ieee.org/futuredirections/2018/06/14/digital-twins-advantages-issues-of-a-powerful-emerging-technology/>; Pei-Hua Huang, Ki-Hun Kim & Maartje Schermer, "Ethical Issues of Digital Twins for Personalized Health Care Service: Preliminary Mapping Study" (2022) 24:1 J Med Internet Res e3308; Eugen Octav Popa et al, "The use of digital twins in healthcare: socio-ethical benefits and socio-ethical risks" (2021) 17:6 Life Sciences Society & Policy; Bergthor Björnsson et al, "Digital twins to personalize medicine" (2020) 12:4 Genome Medicine, online: < https://doi.org/10.1186/s13073-019-0701-3>.

Digital Twins (Abdulmotaleb El Saddik, University of Ottawa / Mohamed bin Zayed University of Artificial Intelligence)

Abdulmotaleb El Saddik, a leading researcher in engineering and computer science with a focus on haptics and human-computer interactions, began by defining "digital twin" as a “digital replica of a living or non-living physical entity.” He described the lineage of technologies leading to their development, including “smart objects” such as fans, locks, and lights aimed at creating a seamless experience between the “real” and the “virtual”, explaining that “digital twins” now play an important role in the digital metaverse.

El Saddik then described the main applications for digital twins, particularly in healthcare, where he said twins could be used to demonstrate the impact of preventative medicine and exercise. He also discussed the possible use of digital twins in a range of other contexts, relating for instance to data ownership and storage, supporting well-being, providing "immortality" (algorithmically-trained digital twins as our virtual legacy) and dating (picture a digital twin driving its smart car through a smart city with the digital twin of their suitor, tasked with determining whether it’s a match).

El Saddik explained that bringing this vision to reality would require significant technological infrastructure. Digital twins require the instant transmission of multisensory content through both soft sensors (including non-physical data such as banking transactions) and hard sensors (coming from physical sources like smart cars). He noted, however, that investing in these developments would fit well into national strategies to promote the use and development of AI, as articulated by countries including France, China, Germany, and Canada.[5]

El Saddik emphasized the prominence of digital twins as an emerging technological trend attracting significant interest and funding. He said the technology has the potential to improve citizens’ well-being and quality of life and to transform business by supporting efficient

[5] See Tim Dutton, Brent Barron & Gaga Boskovic, “Building an AI World: Report on National and Regional AI Strategies” (CIFAR, 2018), online: <https://cifar.ca/wp-content/uploads/2020/05/buildinganaiworld_eng.pdf>.

decision-making. While questions remain about logistical management, legality and liability (including how health data can be twinned when patients do not currently own their data), El Saddik predicted that developers are only one or two years away from creating digital twins for well-being, perhaps drawing on FitBit or sleep data, and that medical twinning capable of cloning organs is probably one or two decades away.

Commentaries

The legal commentaries focused on three issues that have been discussed at previous CIFAR events and that were pre-identified by planners as raising potential issues for digital twins.

A. Liability (Lara Khoury, McGill University)

Lara Khoury began with an overview of some possible advantages of using AI technology such as digital twins in healthcare. These include timely diagnosis and prognosis, reduction of risks and adverse events linked to human error, improved capacity to predict health issues (including prevention or reduction of disease), and treatment optimization. She then went on to explain the need to consider the liability issues that may arise for several actors, including manufacturers; clinicians employing digital twin technology; patients; and even digital twins themselves.

Khoury highlighted the possibility of liability for harms flowing from design defects that cause technology malfunction, poor quality data or biased data sets and algorithms, or insufficient accounting for the environment or usage context. She explained that developers, programmers, and manufacturers could all be liable for patient harm that is caused by such design defects. She observed that parties might make a range of arguments to avoid such liability. For instance, manufacturer / developers might argue there was patient knowledge and acceptance of risks or, conversely, that the developers could not have known of the existence of the defect at the time of the technology's release to the public. She noted that such a defence would be temporary, however, as developer / manufacturers must endeavour to discover defects and release updates in a timely manner. Where defects or inherent risks are known, manufacturers or even clinicians could be liable for failure to inform patients. At the same time, Khoury noted that risk of error is a feature of learning systems, not necessarily a sign of defect or negligence, and that this can complicate the attribution of liability.

Assessing liability in this context involves determining the proper (or reasonable) interaction between human and machine judgement. Khoury explained that if digital twins become the standard of professional practice in the future, clinicians could become liable for failure to use the technology — a possibility that was also raised during other case studies. She also noted that

liability concerns may change over time as ideas about "overreliance" and negligence for failure to use evolve. For instance, some may be comfortable using digital twins as a confirmatory tool but not for the purpose of making predictions to inform decision-making. However, this concern could dissipate as the technology improves and becomes better understood.

Another possible source of liability is the violation of privacy. Khoury also discussed the difficulties of determining causation in misdiagnosis cases and of assigning liability where complex systems with machine learning capabilities are involved. She also noted the possibility of liability for health care institutions and even for digital twins themselves (associated with an insurance obligation), should they eventually be capable of autonomous decision-making.

In terms of regulation, Khoury emphasized the importance of having the liability risks associated with digital twins clearly identified for developers, manufacturers, and healthcare professionals and researchers. The risks identified would change as the technology evolves; however, seeking to keep these updated and clearly identified could help reduce risk before implementation and reassure end users of the technology.

B. Informed Consent (Kate Dewhirst, Private Practice)

Kate Dewhirst began by giving an overview of the law of informed consent.[6] She explained that patients have a right to informed consent to treatment, counselling, research, and collection of data. In all cases consent must relate to the medical decision, be informed, voluntary, and not obtained through misrepresentation or fraud.

A healthcare provider owes a duty of care to the patient to disclose risks associated with treatment and non-treatment, including alternative treatment options. Dewhirst suggested this requirement could become more onerous with the use of technology such as digital twins, because there will be more relevant information about treatment options, risks, and side effects. Dewhirst emphasized the importance of there being meaningful, capable and informed consent for reasons relating to patient autonomy.

Dewhirst then raised a number of questions relating to informed consent in the context of digital twins. She considered, for instance, whether treating a digital twin for experimental purposes

[6] See *Reibl v Hughes*, [1980] 2 SCR 880; *Arndt v Smith* [1997] 2 SCR 539.

would count as treatment, triggering a requirement for informed consent. For example, if a procedure were tested on a digitally-twinned kidney before a patient's surgery, would consent be required from the outset? Similarly, is a digital twin an extension of the individual or a separate legal entity, who might have the right to make a different decision from the individual? Indeed, Dewhirst considered the possibility that a digital twin might be a more reliable decision maker than the individual, and that individual choices could perhaps be challenged if the twin decided differently. She also noted that people might withdraw consent and request that certain aspects of their life not be recorded, creating a possible disparity between the person and their 'twin'. On the other hand, where patients are not always reliable in sharing information relevant to decisions, digital twins could potentially be used as substitute decision-makers to help determine what an individual would want.

Dewhirst also raised questions about ownership of the digital twin, including who consents to its creation, suspension and termination, and whether the twin could be sold, commercialized, inherited, or donated to science upon the death of an individual. She also discussed concerns relating to the history of foregoing consent in medical research for societal benefit (for instance, the case of Henrietta Lacks[7]), and the role that private companies may end up playing in the consent process. She also noted the possibility that wealthy, white patients would be more likely to consent to trials, perpetuating existing discrimination.

C. Privacy (Teresa Scassa, University of Ottawa)

Teresa Scassa began by outlining the likely evolution of digital twin technology from organ to organism, where models become increasingly complex from a privacy perspective. While a digital organ model of a heart or liver may draw on personal health data, a digital twin of an individual would draw data from many different sources, possibly including social media, spending records, and location data. Meanwhile, Scassa explained that privacy law is in the process of evolving, and will be quite different in the not-too-distant future as a result of changes driven by AI and data use.

Health data, public sector data, and proprietary data are currently governed by different regulatory regimes. However, digital twins will theoretically pull these sources together, creating regulatory and ownership tensions. Further, digital twins raise questions about data mobility. Although

[7] Henrietta Lacks's tissue was taken without her consent, from which the widely used HeLa cell line was synthesized. See: Henrietta Lacks: Science Must Right a Historical Wrong, Editorial, *Nature* (1 September 2020), online: < https://www.nature.com/articles/d41586-020-02494-z>.

proprietary data may be extracted by private, for-profit companies, emerging regulatory regimes, including European data protection regulations[8], the federal government's proposed consumer privacy protection legislation[9] and proposed open banking frameworks[10], all emphasize individuals' mobility rights related to personal data as well as their ability to port data from one organization to another. Interestingly, Quebec's Bill 64[11] protects mobility rights related to personal information, but only with respect to data collected from an individual and not proprietary data generated about individuals (such as profiles), underscoring tensions in law likely to come up in the context of digital twins. Data mobility remains a major regulatory question, raising issues for ownership, security, protection from exploitation, control over data and deletion.

Scassa also noted that increased interplay between sectors will mean more power for the private sector, including platform-based health services. Other privacy and data protection issues worth considering include data security, quality, overcollection, retention, and correction. In terms of privacy, digital twins raise issues related to autonomy and the freedom to choose what kind of information is collected, including the freedom to lie to the doctor and decide what information to share. Scassa emphasized that this is a matter of human dignity. Essentially, privacy law is currently being tested by emerging technologies, including those employing AI, and digital twins will exacerbate current challenges.

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[8] EC, Regulation (EU) *2016/679 of the European Parliament and of the Council of 27 April 206 on the protection of natural persons with regard to the processing of personal data and on the free movement of data, and repealing Directive 95/46/EC (General Data Protection Regulation)*, [2016] OJ, L 1119/1.

[9] Bill C-11, *An Act to enact the Consumer Privacy Protection Act and the Personal Information and Data Protection Tribunal Act and to make consequential and related amendments to other Acts,* 2nd Sess, 43rd Parl, 2020 (first reading completed 17 Nov 2020), online: <https://www.parl.ca/LegisInfo/en/bill/43-2/c-11>. After this case study event a revised version of the bill was introduced, Bill C-27, *An Act to enact the Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act and the Artificial Intelligence and Data Act and to make consequential and related amendments to other Acts*, 1st Sess, 44th Parl, 2022 (introduction and first reading, 16 June 2022), online: <https://www.parl.ca/legisinfo/en/bill/44-1/c-27>.

[10] See Senate of Canada, *Report of the Standing Senate Committee on Banking, Trade and Commerce* (June 2019).

[11] Bill 64, *An Act to modernize legislative provisions as regards the protection of personal information*, 1st Sess, 42nd Leg, Quebec, 2020 (assented to 22 September 2023), SQ 2020.

Breakout Sessions

The commentaries were followed by breakout sessions on (1) liability, (2) privacy, and (3) informed consent. Rapporteurs then summarized the findings during a debriefing session. The core thematic concerns that arose in each session are summarized below.

Breakout #1: Liability

Attendees: Vanessa Gruben (Rapporteur), Sarah Lazin (Scribe), Marc Bilodeau, Tania Bubela, Michael Froomkin, Geneviève Lavertu.

The breakout group focused on (1) liability for the digital twin, (2) liability for healthcare providers, (3) product liability, (4) causation, and (5) next steps.

I. Liability for the digital twin

The group began by discussing potential liabilities that could apply to the digital twin itself, and whether it could be considered an autonomous member of a multidisciplinary care team, making decisions about a patient's healthcare. The group suggested the digital twin might be protected from liability if it were not the sole decision maker, and / or if it simply provided information that factored into team-based decision making for the benefit of the patient.

The group also discussed the possibility that liability for the digital twin may move in the opposite direction, with manufacturers or clinicians owing a duty of care as co-creators of the digital twin. The question became: is the digital twin a member of a team that owes a duty of care to the patient, or is the digital twin in fact a doppelgänger of the patient to whom a duty of care is owed?

II. Potential liability for healthcare providers

Considerable discussion centred around new liabilities that digital twins could impose on health care providers. One group member noted doctors are often worried about there being a "tsunami of data" they are responsible for staying on top of and for which they may be liable. Members noted that clinicians might not understand all the parameters or meanings of the AI generated data and discussed the importance of having responsibilities and duties of care clearly specified,

especially if clinicians are to be potentially liable for missing or misinterpreting data signals. The group discussed several parallels in existing medicine, including point-based alternative data and patients having access to their own charts, which some clinicians are already uncomfortable with given the additional workload and liability risk without additional pay.

III. Product liability

Discussions also turned to product liability and regulation, including whether digital twins would be considered medical devices or, perhaps, akin to non-invasive wearable technologies like Fitbits and Apple Watches. Participants noted this may depend on whether digital twins are being used to collect data or draw conclusions through an algorithm. The group discussed whether current regulatory frameworks are sufficient, and the extent to which manufacturers might want (or not want) digital twins to come under particular regulatory umbrellas.

IV. Causation

The breakout group also discussed the difficulty of determining causation in cases of harm from AI and the resulting challenge of assigning liability among possible actors (including developers, clinicians, patients, and digital twins themselves). The group also discussed biohacking and the challenges that might arise where patients modify device algorithms or inputs, in a way that might even constitute contributory negligence for any resulting harm. Some members found it helpful to draw on the example of glucose monitoring devices, which combine measurements with predictive intelligence and are already in wide use, to frame the liability and causation issues potentially arising from digital twins.

V. Next steps

The group briefly discussed, but did not agree on, whether new frameworks and laws would be needed to address the liability issues arising from digital twins. Some suggested the need for new law, while others thought current regulatory frameworks could be adapted without a complete overhaul, especially as new technologies like digital twins are introduced incrementally.

Breakout #2: Informed Consent

Attendees: Catherine Régis (Rapporteur), Nicole Davidson (Scribe), Jason Millar, Abdulmotaleb El Saddik, Jennifer Gibson, Colleen Flood, Ian Stedman, Kate Dewhirst, Melissa McCradden

The informed consent breakout group focused on four main topics: (1) defining the digital twin concept in relation to consent, (2) ensuring that the goals of data collection are clear, (3) adapting to change over time, and (4) the implications of the technology on clinical interactions.

I. Defining the digital twin concept

The group began by noting that thinking about informed consent first requires a clear definition of digital twins. One participant noted the concept is amorphous and abstract, and that a digital twin would probably comprise multiple datasets and representations (with a better metaphor being, perhaps, digital fraternal triplets or octuplets). Participants thought the multifaceted nature of digital twins, as well as their capacity to evolve over time, makes it difficult to determine what an ongoing, informed consent structure might look like. They noted, for instance, that data can already be pulled from both medical encounters and social media, with varying degrees of anonymization and consent.[12]

II. Goals of data use

The group discussed the related challenge of ensuring that collected data will be used to benefit the patient, and that patients are consenting to all its uses. They noted that regulators will need to ensure that digital twins are being used for the intended purposes — e.g. to increase quality of care — rather than by insurers, banks, or employers for unwanted purposes such as denying benefits or employment. One participant suggested that Canada's *Genetic Non-Discrimination Act* might be a good model for ensuring the public benefit of data collection.[13]

III. Adapting to change over time

As consent is an ongoing process and digital twins could theoretically be used over the course of a patient's lifetime, the group discussed the importance of ensuring that digital twins adapt to

[12] See March 11, 2022 Machine MD case study on Suicide Artificial Intelligence Prediction Heuristic (SAIPH) for more on consent structures for predictive analytics tools using public social media data.

[13] *Genetic Non-Discrimination Act*, SC 2017, c 3.

patients' evolutions over time. Members were concerned about the possibility of a divergence between the data collected for a digital twin and the person's actual interests and circumstances as they age.

IV. Implications for clinical interaction

The group discussed the possible effects of digital twins on the relationship between patient and health care practioner. One participant raised the possibility that clinicians might listen to the digital twin over the patient, perhaps making clinical discussions more difficult. Another participant noted that the outcome could be positive and could improve the ease of communication for some, for example, in situations where negative clinical interactions are marked by stigma or shame.

Breakout #3: Privacy

Attendees: Pascal Thibeault (Rapporteur), Arianne Kent (Scribe), Anna Goldenberg, Caroline Mercer, Sophie Nunnelley, Christian Blouin, Teresa Scassa, Christina Gilman, Florian Martin-Bariteau, Regi Garcia.

This breakout group began with a discussion of cybersecurity and digital twins. One participant noted that hacking, system access, and identity theft have increased in recent years. It was noted that while health data security issues are not new legal issues, the scale has perhaps changed with increased cyber and ransom-ware attacks. Digital twins are also intended to collect data from multiple sensors that go beyond health data, including from consumer devices with lesser security. The group noted that these are not novel issues, but that digital twins may augment the scale of the problem. The group also considered who ought to be responsible for these issues. For instance, there was some discussion about whether cybersecurity issues are within the purview of AI and digital twin developers, or whether these issues should be kept separate and made the concern of hospital Chief Information Officers, for example.

The group also discussed the importance of building public trust when asking patients to share their data, acknowledging that it is impossible to fully guarantee that data will be safe. This is especially pressing given the frequency of media reports on data breaches. They noted that public engagement and transparency are important tools for integrating patients and building trust in the technology.

There was some discussion of the possible risks to patients from digital twins, including risks relating to identity theft and use of data by insurers and employers. One participant expressed concern that digital twins would be created by private, for-profit industry, whose primary purpose is monetary enrichment. However, participants also considered that private industry, when regulated correctly, benefits individuals through the fast progress it drives. Another expressed concern was that patients could encounter issues when trying to correct inaccurate data in their digital twin's "medical record."

Finally, the group briefly discussed data ownership and data sovereignty for Indigenous communities, emphasizing data control, capacity-building and self-governance. A participant suggested that decisions regarding the terms of data sharing should be made within a self-governance framework.

Conclusion

This case study brought to light many legal issues — relating to privacy, informed consent, and liability — that potentially arise out of the use of digital twins in healthcare. It also allowed for an in-depth conversation about the ability of current law to address these challenges and the optimal form of governance in this context. Among the many questions and themes raised during the presentations and breakout sessions were the following:

- Defining the concept of "digital twin." Is it an autonomous entity capable of taking on liability, or an extension of the patient? And is it a single representation or a combination of multiple proprietary datasets pulling from different locations, more like "fraternal digital quadruplets"?
- Data ownership and portability, including who consents to creation, suspension and termination of a digital twin's existence
- The suitability and required evolution of privacy laws
- Accounting for change over time and possible divergence between the objectives of a patient and their digital twin
- Interplay between public, private and health sectors
- Algorithmic bias, unequal access to the technology, and the possible perpetuating of inequalities
- Difficulties in integrating additional data into clinical delivery, including hesitancy from clinicians concerned about taking on additional liability
- Liability flowing from product and design
- The eventual possibility that digital twins may become the standard of care and that liability would flow from failing to use them

- The distinction between using data to inform clinical decisions versus relying on algorithmic decision making

- Complexity in tracing liability in complex systems

This list is non-exhaustive. Some concerns were unique to particular breakout sessions. However, discussions regarding (i) defining the “digital twin” concept and its role, (ii) implications for healthcare providers, (iii) applicability of current regulatory regimes, (iv) patients’ needs versus the needs of private companies, and (v) data ownership and privacy, arose across breakout groups.

Digital twins still exist only as a concept and are several years away from development. Some of the questions raised during this event may be answered as the technology moves closer to realization. As well, regulatory structures for privacy and data ownership change rapidly and are in flux. As frameworks adapt to new technologies like AI and overlapping concepts including algorithmic bias and AI personhood continue to develop, strategies for governing digital twins may become clearer.

This case study, along with the previous OR Black Box and SAIPH case studies, highlights the unique regulatory issues that arise in the context of AI in healthcare, and underscores the importance of further study.

Workshop Participants:[14]

Caroline Mercer	Gagan Gill	Pascal Thibeault
Nicole Davidson	Geneviève Lavertu	Regi Garcia
Colleen Flood	Ian Stedman	Sarah Lazin
Abdulmotaleb El Saddik	Jason Millar	Sophie Nunnelley
Anna Goldenberg	Jennifer Gibson	Teresa Scassa
Arianne Kent	Kate Dewhirst	Vanessa Gruben
Catherine Régis	Lara Khoury	Tania Bubela
Christian Blouin	Marc Bilodeau	
Christina Gilman	Melissa McCradden	
Florian Martin-Bariteau	Michael Froomkin	

[14] Gagan Gill participated in this workshop but was not part of a breakout session.

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