Quantum Trials: An FDA for Quantum Technology

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Authors

Alexandra Waldherr
Stanford Center for RQT
Medical University Innsbruck, University of Innsbruck
alexandra.waldherr@student.i-med.ac.at

I. Glenn Cohen
Harvard Law School
igcohen@law.harvard.edu

Mauritz Kop
Stanford Center for RQT
Stanford Law School
mkop@stanford.edu

Author Biographies:

Alexandra Waldherr is part of the Space Medicine team at the European Space Agency. Her practical experiences range from work with BASF, the Austrian Center for Molecular Medicine and the European Synchrotron Radiation Facility to CERN. She holds a degree as Chemical Engineer and is currently finishing her MSc. in Drug Development and Regulatory Affairs (with a BSc. in Physics on the side) and starts her doctorate at Max Planck in autumn 2024. Alexandra serves as Fellow at the Stanford Center for Responsible Quantum Technology, her passion for quantum computing has grown in projects since 2018. She has advised the German Stifterverband on establishing quantum educational curricula and the Austrian Quantum Machine Learning initiative on quantum simulation. Alexandra presented a first version of the *Quantum Trials* framework and the SEA TURTLE principles at the Stanford Responsible Quantum Technology Conference in 2023.

I. Glenn Cohen is the Deputy Dean and James A. Attwood and Leslie Williams Professor of Law, Harvard Law School and Faculty Director, Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics. He is the author or co-author of over 200 scholarly articles in leading journals in law, medicine, science, and bioethics. Glenn is the author, co-author, editor, or co-editor of more than 18 books on the intersection of law and medicine. His work was supported in part by a Novo Nordisk Foundation Grant for a scientifically independent International Collaborative Bioscience Innovation & Law Programme (Inter-CeBIL programme - grant no. NNF23SA0087056). He serves on the bioethics advisory board of Illumina and on the bioethics council of Bayer and has compensated for speaking at an event organized by Philips and the Washington Post. He has also been retained as an expert witness in health data privacy litigation.

Mauritz Kop is the Founding Director of the Stanford Center for Responsible Quantum Technology, and a Stanford Law School TTLF Fellow at Stanford University. He is also Founder of MusicaJuridica, Director at AIRecht, and General Counsel at Daiki, a Vienna and Palo Alto headquartered unified SaaS platform committed to building a Trustworthy AI future. Promoting good governance, Mauritz helps nations across the world to develop Responsible Quantum Technology and Innovation strategies. His interdisciplinary academic work on regulating AI, machine learning training data, intellectual property, and the suite of quantum technologies has been published in leading scholarly and peer reviewed journals across the globe.

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Abstract

Quantum technology (QT) development and adoption by the markets promises high innovational rewards but is not yet sufficiently guarded by legal and ethical guidelines. Educational barriers remain high, while risk/benefit curves need to be optimized. In this article, we propose a phased regulatory framework for regulators to incentivize (or mandate) responsible development of novel QTs. Inspired by the way how policy makers and legislators have approached the problem of market approval in the pharmaceutical space, we draw parallels to stages in QT research and development: The FDA Clinical Trial model – three phases that precede market authorization, followed by a fourth post-approval stage – can be translated into an analogous structure to assess quantum developments. We propose the instatement of a federal agency which can guide, structure and market-authorize second generation (2G) QT. Our proposal, inspired by the clinical registry, hopes to set the table for regulating emerging quantum technologies.

I. Introduction

Since James Lind ran what was arguably the first clinical trial, the approval of drugs has grown into a strictly supervised endeavor. No longer can sick patients be treated with remedies, as in those days, randomly selected on a ship.[1] Rather, vigilance practices and regulatory frameworks provide structure and guidance. Repeatedly in history, several types of regulatory frameworks have been put into place to guide young technologies. This was particularly important in highly innovative fields, such as, aviation, life sciences, drug development – or currently for artificial intelligence. Here, high innovational rewards come in tandem with high uncertainty of outcome.

Currently, the beginnings of a new technological group are being established: Second generation (2G) quantum technologies (QT).[2] The stark difference to first generation (1G) QT is an inclusion of novel discoveries from the field of *quantum information science*, discoveries that lie at the intersection of *quantum mechanics* and *information technology*. These fields alone have impacted the 20th century majorly. Quantum mechanics lies more hidden from the eyes of general citizens, but information technology encompasses computers, networks and software. Processes we use daily to create, process or store data.

We can thereby differentiate *"quantum technologies"* (QT) into 1G technologies, which utilize quantum effects, and 2G technologies which actively bring in information science to construct and manipulate quantum states. As a prominent example, atomic clocks fall into the category of 1G QT. They use energy levels of atoms, preset by nature, to clock our time.[3] On the other hand, quantum computers fall into the category of 2G QT: They

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[1] James Lind, *Treatise of the Scurvy in Three Parts*, via the JAMES LIND LIBRARY: https://www.jameslindlibrary.org/lind-j-1753/

[2] NIST, *The Second Quantum Revolution*, https://www.nist.gov/physics/introduction-new-quantum-revolution/second-quantum-revolution

[3] An atomic species can undergo transition between defined energy levels. One may imagine it an elevator traversing between two "quantized" levels: It requires a precise input to occur successfully. This exact energy can be inputted by an electromagnetic wave of exact frequency. The reciprocal of a frequency gives a time unit. By harnessing energy levels preset by nature, we guard a precise frequency to calibrate timekeeping devices.

consist of software (= quantum algorithm) that actively induces change on tailored quantum hardware (= qubits).

As we move from 1G QT (building on natural states) towards 2G QT (creating, constructing, and manipulating quantum states) the educational barrier and the risk potential rise. This calls for regulators to identify a structure that can accommodate these new advances in the best way possible. Specifically, a structure is sought that is adaptive enough to grow with the young technology, while at the same time applies brakes early enough to safeguard societal values, both at the national level and in global cooperation.

Three core pillars arise: *Researchers*, who decide which ideas are followed and developed. *Regulators*, who weave developments into (national) society, and *global consortia*, who decide which developments are ethically allowed for the benefit of humanity.

The U.S. sets leading positions in the first pillar.[4] Both academic institutions and large private companies dominate quantum information sciences and quantum computing. On the academic side, MIT is particularly strong with Peter Shor, who invented "Shor's Algorithm" and opened a way for quantum computers to theoretically being able to break and endanger traditional encryption. Peter Shor's publication[5] ignited international attention on the power and potential harm – the benefits and risks – quantum computers hold for citizens.

On the private side, IBM provides the largest open-access quantum computing cloud platform today.[6] Most people can log on to quantum computing backends from their couch. At the same time, IBM and Google provide the two most comprehensive online textbooks for quantum computing and two widely used open-source programming frameworks, Qiskit and

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[4] McKinsey & Company, *Quantum Technology Monitor by April 2023*, https://www.mckinsey.com/de/~/media/mckinsey/locations/europe%20and%20middle%20east/deutschland/news/presse/2023/2023-04-24%20qt%20monitor%202023/quantum-technology-monitor-april-2023.pdf

[5] Peter W. Shor, *Algorithms for Quantum Computation: Discrete Logarithms and Factoring*, PROC. - ANNU. IEEE SYMP. FOUND. COMPUT. SCI. FOCS 124 (1994)

[6] IBM, *IBM Quantum Platform*, https://quantum-computing.ibm.com/

Cirq.[7,8] By this, they are not only shaping global access dynamics but also the public's education and perspective on QT impactfully.

On the second and third pillars, national regulation and global ethical agreements respectively, we see much less progress both in the U.S. and outside of it. The main legal documents in the U.S. include the "National Quantum Initiative Act" of Congress (2018),[9] two executive orders to safeguard against cybersecurity breaches by a quantum algorithm (2022),[10,11] and one executive order on investment in national security technologies (2023).[12]

The "National Quantum Initiative Act" is the most important of these laws, establishing the National Quantum Initiative (NQI), a National Quantum Coordination Office, a Subcommittee on Quantum Information Science, and a National Quantum Advisory Committee.[13] The National Quantum Coordination Office, located in the White House Office of Science and Technology, is the main executive branch actor in this field. One of its main tasks is "promoting [the] access to and early application of the technologies, innovations, and expertise derived from NQI program activities."[14] This work is just beginning, and part of the purpose of this paper is to try to suggest the best scaffolding to aid these efforts.

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[7] Qiskit, *Qiskit Textbook*, https://learning.quantum.ibm.com/
[8] Google Quantum AI, *Textbook algorithms in Cirq*, https://quantumai.google/cirq/experiments/textbook_algorithms
[9] Lamar [R-TX-21] Rep. Smith, *Text - H.R.6227 - 115th Congress (2017-2018): National Quantum Initiative Act* (2018), https://www.congress.gov/bill/115th-congress/house-bill/6227/text
[10] The White House, *National Security Memorandum on Promoting United States Leadership in Quantum Computing While Mitigating Risks to Vulnerable Cryptographic Systems*, https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/04/national-security-memorandum-on-promoting-united-states-leadership-in-quantum-computing-while-mitigating-risks-to-vulnerable-cryptographic-systems/
[11] The White House, *President Biden Announces Two Presidential Directives Advancing Quantum Technologies*, https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/04/fact-sheet-president-biden-announces-two-presidential-directives-advancing-quantum-technologies/
[12] The White House, *Executive Order on Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern*, https://www.whitehouse.gov/briefing-room/presidential-actions/2023/08/09/executive-order-on-addressing-united-states-investments-in-certain-national-security-technologies-and-products-in-countries-of-concern/
[13] National Quantum Coordination Office, *National Quantum Initiative*, https://www.quantum.gov/
[14] National Quantum Coordination Office, *The National Quantum Coordination Office*, https://www.quantum.gov/nqco/#THE-NATIONAL-QUANTUM-COORDINATION-OFFICE

B. Which regulatory structure can fit quantum technologies?

Ideally, a quantum regulatory framework should easily integrate into the existing workflows of researchers, industry, and the public alike. Intuitively, the three pillars from *researcher → regulator → to global committees* describe a trajectory of growth. An idea starts early stage in a laboratory. From there it is refined, and an optimized version later may later be launched as a successful product. This observation sparked us to think of quantum developments inside a framework being comparable to drugs' authorization process. The FDA process guides drugs from the lab bench to the patient in four stages, focusing on safety and efficacy.

Similar to the pharmaceutical domain, QT constitute a wide, yet narrow, field. Stakeholders – in a "T"-shaped fashion – deal with a broad variety of concepts while at the same time highly specialized knowledge is needed to realize the development of one quantum device. Therefore, new regulatory affairs would ideally map onto well-established, globally understood workflows, to foster efficient communication between all parties. The FDA process is a good "originator" for this situation, on which to draw from in thinking about an optimal workflow for regulating today's and tomorrow's QT.

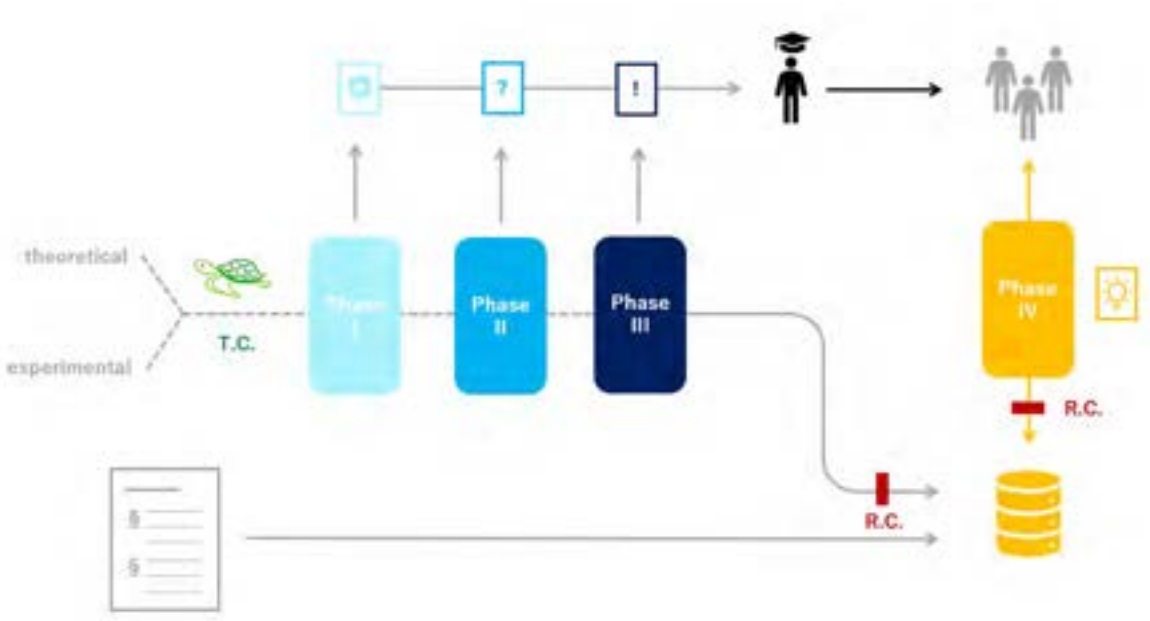

Figure 1: **A regulatory framework for QT.** Depicted is a possible overarching pipeline for quantum technologies (QT), developed with the *Quantum Trial* framework. Central to the framework are four *phases*. One phase leads to the next, each concludes with standardized documentation. From the beginning, we recommend a binding registration, thereby all data would flow in a structured registry/database (bottom right). New QT (start left) begin as *theoretical* idea or *experimental* observation. Phase I – III investigate details further and document findings in i) a technical one-pager (indicated by ⚙), ii) an ethical checklist (**?**) and iii) the *Summary of Quantum Characteristics*, SmQC (**!**) respectively. These documents are hosted in a database and will be directly used by educators (black) to update curricula effectively and pass information to the public (grey). A matured technology reaches the public in Phase IV. Regulatory check (R.C., red) grant QTs access to the market. Phase IV follows the quantum product's lifecycle between public, educators, and technology owner. R.C. audits ensure real-world integration and optimization. At any stage, technical checks can be made at with the SEA TURTLE framework (T.C., green).

II. Quantum Technologies (QTs) Today

In an intuitive way, QT can be classified along three measures: The *first measure* is 1G vs. 2G technologies. This differentiation was briefly explained in Section I, with atomic clocks being one example for 1G technologies and quantum computers one example for 2G QT. In essence, a 1G quantum technology is built from hardware piece naturally exhibiting quantum phenomena (e.g. atomic clocks, lasers, MRI-scanners), while for 2G quantum technologies, the intention to manipulate, enhance and tune quantum effects lies at the core of the design. Quantum states and the hardware itself get actively modified (e.g. quantum computers).[15]

The *second measure* is to consider whether a quantum device concerns hardware or software. Sometimes the differentiation might be slightly altered to think *experimental* vs. *theoretical* design. This discussion is often not touched, it being automatically implied that a "technology" describes a materialistic device. However, in the context of "quantum technology" both innovational steps are possible and understanding whether a QT brings theoretical or engineering advancement will affect the educational background a regulator requires. Utilizing this classification, quantum computers can be distinguished into hardware (= qubits) and software (= quantum algorithms). One is the medium, the other the logic.[16]

The *third measure* is to differentiate by field of physics and applicational classes. In the case of quantum computing algorithms, talking to a hardware technician the investigated classes are, e.g., superconducting circuits, ion traps, photonics. On the software side, common applicational classes can be listed to be quantum simulation, quantum optimization, quantum

[15] Jonathan P. Dowling & Gerard J. Milburn, *Quantum Technology: The Second Quantum Revolution*, 361 PHILOS. TRANS. R. SOC. LONDON. SER. A MATH. PHYS. ENG. SCI. 1655 (2003)

[16] Between the two categories, possible risks are different. The biggest threat for *hardware* is malfunctioning, the breaking down of a component. The biggest threat for an *algorithm* is wrong logic or an attack injecting bad intent into the running production.

cryptography, quantum machine learning. Visually, all different fields of physics may be displayed as a hierarchical map, with QT being one of the *subdisciplines*.

A. A Map, Subdisciplines and Topics

The terms *quantum physics*, *quantum technology (QT)*, *quantum engineering (QE)* and *quantum computing (QC)* may be confusing when new to the field. A nice way to comprehend these hierarchically, is to understand "quantum physics" as an *umbrella* term spanning different *subdisciplines*: Those *subdisciplines* being QT, QE, quantum information science, or quantum chemistry, to name a few. In the last years, it became evident that QT and QE need to be educated together to form the future workforce. Combined the two subdisciplines are often abbreviated as QT&E.[17]

Through all *adjacent subdisciplines*, every QT *topic* is fed with new ideas and can grow them into *practical applications*. Classical industries – like the chemical, aerospace, or automotive industry – might as well spark new ideas that migrate to the QT domain. One *topic* therefore holds multiple concrete QT *applications* in development. These QT ideas require quantum engineering to be realized into full technological devices. Overall, QT is one subdiscipline of quantum physics, the one where "quantum physics is made practical".

[17] Abraham Asfaw et al., *Building a Quantum Engineering Undergraduate Program*, 65 IEEE TRANS. EDUC. 220 (2022)

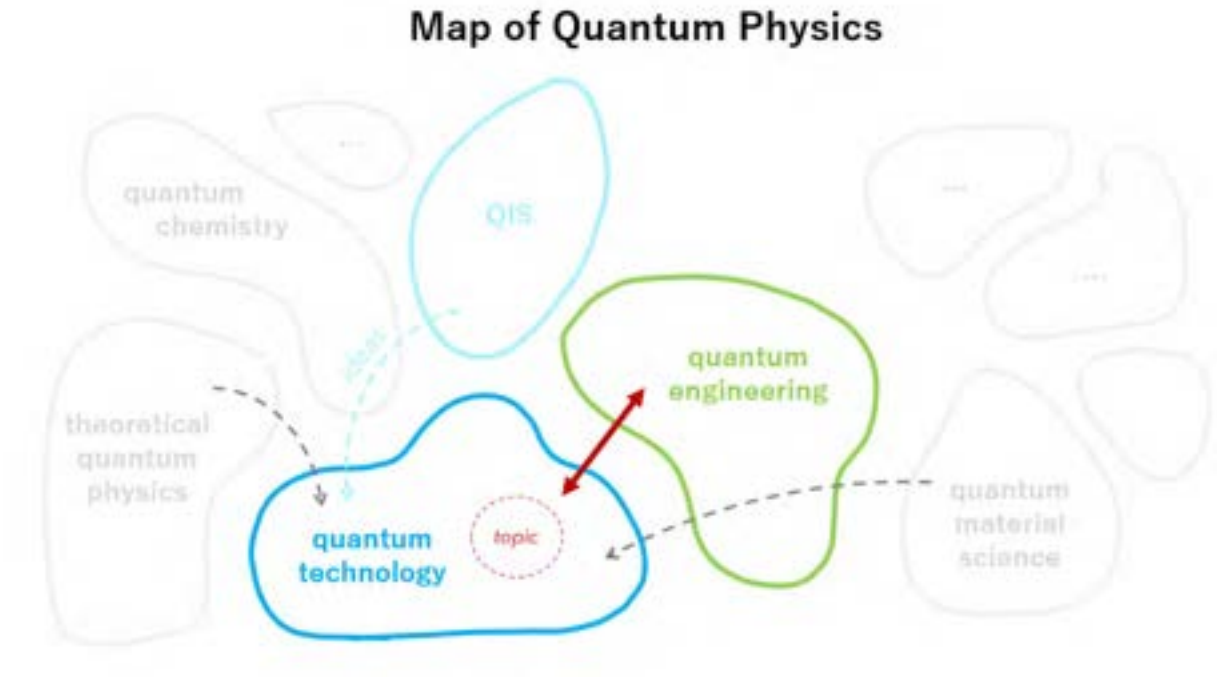

Figure 2: **Map of Quantum Physics.** An agreed taxonomy of quantum technology (QT) is currently lacking. We propose a top-down understanding from *quantum physics → subdiscipline → topic → application (device/algorithm)*. One regulated unit, a "filed" QT, would sit at the finest granularity level: It would be one concrete *application* sitting inside one *topic* area. The red arrow highlight how quantum technology (QT) can only be realized together with the field of quantum engineering (QE). The grey arrows visualize that 2.0 QT innovation may start or be often catalyzed by *theoretical ideas* or *experimental observations* in other subdisciplines. The map was inspired by the informal art "Map of Physics" Dominic Walliman.[18]

The six *topics* comprised under 2G quantum technology are: *quantum computers*, *quantum algorithms*, *quantum cryptography*, *quantum networks*, *quantum simulation* and *quantum sensing*. Each topic holds its own set of applications, with quantum computers and quantum metrology (used here interchangeably with the term quantum sensing) being more

[18] Visit: https://dominicwalliman.com/post/153828312160/here-is-the-map-of-physics-as-an-image

on the experimental side. Quantum algorithms, simulation, cryptography and networks lean towards theoretical concepts.

These six classes are not universally agreed on. To our knowledge, no international ontology exists to date. Rather, we offer this categorization as first international standard taxonomy for regulators, established from agreement between large educational statements from top universities, roadmaps for educational programs, the NQI, and the European Patent Office.[19,20,21,22] We summarize the current state of each topic in a rather technical Topic Box. Modifications and discussions are warmly welcomed.[23]

Topic Box

1. Quantum Computers Today

When we compare the beginning of the classical computing era to today, wires and vacuum tubes (and literal bugs[24]) have made room for stable transistors. For quantum computers, we are not there yet. There is no one universal, stable quantum hardware architecture agreed on so far. Instead, quantum systems can have very different properties – there are natural ones, like ions, or manufactured ones, like superconducting circuits. The first type has the benefit to be reproducible stably around the globe, while for the second type the producer can design properties to his or her benefit. In contrast to transistors, who are the hardware representation to hold a classical bit, it has not yet been decided which type of

[19] European Patent Office, *Patent insight reports*, https://www.epo.org/en/searching-for-patents/business/patent-insight-reports
[20] ETH Zurich, *Curriculum – Master in Quantum Engineering*, https://master-qe.ethz.ch/education/curriculum.html
[21] TUM Technical University of Munich, *Quantum Science & Technology - Master of Science (M.Sc.)*, https://www.tum.de/studium/studienangebot/detail/quantum-science-technology-master-of-science-msc
[22] UCL University College London, *Module Catalogue: Advanced Quantum Devices (PHAS0114)*, https://www.ucl.ac.uk/module-catalogue/modules/advanced-quantum-devices-PHAS0114
[23] Please reach out to the Stanford Center for Responsible Quantum Technology for direct communication and further information.
[24] Virgina Tech by Sharron Ann Davis, *Rear Admiral Grace Murray Hopper*, https://ei.cs.vt.edu/~history/Hopper.Danis.html

hardware is the best in terms of stability, usability, and scaling, to hold and maintain a quantum bit – a *qubit*.

At IBM, Google and other companies, one can find the infamous "golden chandelier" of quantum computers, extensive wires frame circuits on a quantum processing chip. They represent a predominant rise of one type of manufactured qubit among industry: *superconducting transmon qubits*. Physically, they are tiny oscillating circuits with a junction of insulating material, to oscillate at two distinct energy levels, able to be in superposition of both. In essence, such a qubit is the smallest computation unit of the quantum computer, and multiple units sit on a quantum chip. Five to over a thousand qubits can be present and comprise the *qubit register*. Multiple *physical qubits*, that naturally are error-prone, can be combined into a smaller set of *logical*, error-corrected, qubits. The number of physical qubits therefore delivers no perfect benchmark. Apart from error correction, connectivity among qubits is another key ingredient to build computation. To implement algorithms, interaction of the quantum system ("qubit register") with energy pulses ("quantum gates/operations") is necessary. In the case of superconducting qubits, the incident energy are microwave pulses.

Other hardware architectures are *ion traps*, *quantum dots*, *diamond vacancy centers* or *photonic architectures*.[25,26] For example, the Chinese quantum computer, Jiuzhang, utilizes a photonic architecture.[27] In the U.S., IBM leads the delivery of universal quantum computing; their latest processor being the 1,121-qubit 'Condor',[28] the latest available system the

[25] National Academy of Sciences, Engineering, and Medicine, *Quantum Computing: Progress and Prospects*, Chapter 5 (2019)
[26] European Quantum Internet Alliance, *Our Prototype Network, On Metropolitan Networks: Processing Nodes*, https://quantuminternetalliance.org/our-prototype-network/
[27] Zhong, H.-S., Wang, H., Deng, Y.-H., Chen, M.-C., Peng, L.-C., Luo, Y.-H., Qin, J., Wu, D., Ding, X., Hu, Y., Hu, P., Yang, X.-Y., Zhang, W.-J., Li, H., Li, Y., Jiang, X., Gan, L., Yang, G., You, L. and Wang, Z., *Quantum computational advantage using photons*. Science, 370(6523), doi: https://doi.org/10.1126/science.abe8770, (2020).
[28] IBM and Nature, News Release: *IBM releases first-ever 1,000 qubit quantum chip*. Nature, 624(238), doi: https://doi.org/10.1038/d41586-023-03854-1 (2023), Press Release: https://research.ibm.com/blog/quantum-roadmap-2033

Quantum System Two.[29] European researchers at the University of Innsbruck have utilized ion trap quantum computers, which together with the whole periphery can fit inside two server racks and operate at room temperature.[30,31] Normally, quantum computers – while being called "quantum" – take up substantial space due to cooling and shielding requirements.

Physical size, material and monetary requirements suggest that the public will continue to interface quantum computers mostly via the cloud. To provide benchmarks for quantum agents, IBM researchers propose the "quantum volume", a measurement on ability and stability of a quantum processor.[32] Technical disadvantages (e.g., the notorious instability of quantum systems and therefore qubits) can be balanced by constructing quantum-classical hybrids. The classical agent can store data, the quantum agent can take over expensive calculations.

2. Quantum Algorithms Today

Coming from hardware to software, an important concept binding together both is that we are currently in the *NISQ* era (= noisy intermediate-scale quantum). This means that full error correction is not possible, and most hardware is too small to demonstrate significant quantum algorithmic advantages. In other words, hardware incapabilities require protocols to be run and assessed only on pilot-scale. While this is a bottleneck for engineers, it acts as a *brake on innovational speed* and *gifts regulators valuable time windows* to discuss ethics and set up regulatory structures now before scaled-up technology surpasses us and path dependencies prevent efficient policy interventions.

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[29] IBM, *IBM Unveils 400 Qubit-Plus Quantum Processor and Next-Generation IBM Quantum System Two*, https://newsroom.ibm.com/2022-11-09-IBM-Unveils-400-Qubit-Plus-Quantum-Processor-and-Next-Generation-IBM-Quantum-System-Two

[30] Compact quantum computers for server centers – Universität Innsbruck, https://www.uibk.ac.at/en/newsroom/2021/uantum-computers-for-server-centers/

[31] I. Pogorelov et al., *Compact Ion-Trap Quantum Computing Demonstrator*, 2 PRX QUANTUM (2021), https://www.uibk.ac.at/en/newsroom/2021/uantum-computers-for-server-centers/

[32] Keith Miller et al., *An Improved Volumetric Metric for Quantum Computers via More Representative Quantum Circuit Shapes* (2022), https://arxiv.org/abs/2207.02315v2

Coming back to concrete algorithmic implementations, proposals on quantum optimization are highly interesting for industry: These include Variational Quantum Eigensolver (VQE), Quantum Approximate Optimization Algorithm (QAOA) and Quadratic Unconstrained Binary Optimization (QUBO) executions which offer potential pathways to address tasks in logistics, computational chemistry and cryptographic protocol design.[33,34,35] Especially *quadratic programs* offer more and more unified formulation of optimization tasks without the user having to specify a quantum pipelines.[36] Ansatzes or parameterized circuits form a link between quantum computing and quantum machine learning. These are quantum circuits which utilize gates fed with parameters in an iterative way. Example tutorials are openly available, e.g. in the textbook by Qiskit.[37,38]

It may already has come the era, where quantum gates are too "technical" (in the sense of too "low-level" in the computing stack) for regulators or the general user. Only briefly: In general, any quantum algorithm consists of quantum gates (math. matrices) which operate on a quantum state (math. vector) to create a subsequent quantum state (math. vector) in the calculation. On hardware, e.g., this translates to laser pulses being shot onto an ion trap qubit to change the energy of its outermost electron from one energy level into another.

In many cases, the finesse of quantum algorithm relies in translating real-world input into a gate-model that is well-executable on available quantum backends. Statistical

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[33] Dmitry A Fedorov et al., *Fedorov et Al. VQE Method: A Short Survey and Recent Developments*
[34] AWS Quantum Technologies Blog, *Constructing an "end-to-end" quantum algorithm: a comprehensive technical resource for algorithms designers*, https://aws.amazon.com/de/blogs/quantum-computing/constructing-end-to-end-quantum-algorithm/
[35] Alexander M Dalzell et al., *Quantum Algorithms: A Survey of Applications and End-to-End Complexities* (2023)
[36] Qiskit textbook, *Quadratic Programs*, https://qiskit-community.github.io/qiskit-optimization/tutorials/01_quadratic_program.html#
[37] The Qiskit textbook is currently under construction and moves between the Qiskit and the IBM Quantum Platform's websites. Therefore, the GitHub links in references 37, 39 are provided as most stable current sources.
[38] Qiskit GitHub, *Qiskit Community Textbook*, https://github.com/qiskit-community/qiskit-textbook

knowledge is necessary to interpret measurement results and translate them correctly back to the problem of interest.[39,40]

Qiskit allows to specify quantum states, specify custom gates, build quantum circuits, execute them on real quantum backends, and analyze measurements. For the design of a quantum program, one can use circuit diagrams, subroutines, or one-line code functions. High-level implementations, like the mentioned quadratic programs, are possible too. Being the most predominant quantum computing software development kit (SDK), it is supported by an open-source international community and builds onto Python.[41,42] Qiskit connects to the IBM Quantum Platform, where free cloud access to real quantum computer backends and simulators is provided to the general public. Cirq is a comparable framework from Google and provides connections to chemistry and machine learning with the OpenFermion and the Cirq TensorFlow libraries.[43]

3. Quantum Cryptography Today

Quantum cryptography encompasses two concepts of hot interest to industry: i) traditional encryption could be broken with Shor's algorithm and ii) secure transmission (where eavesdropping reveals itself) is made possible with QKD (quantum key distribution). On the first point, NIST has made a thorough effort to avoid a privacy-threatening post-quantum world. Four quantum-safe algorithms were appraised in a selection campaign that ranged six years: CRYSTALS-KYBER for public-key encryption, and CRYSTAL-DILITIUM, FALCON and SPHINCS+ for digital signatures.[44] We see: For different use

[39] Robin Blume-Kohout, *Old-Fashioned Statistics for Modern Quantum Computing*, https://www.osti.gov/servlets/purl/1643421 (2019)
[40] Yazhen Wang & Hongzhi Liu, *Quantum Computing in a Statistical Context*, Annual Review of Statistics and Its Applications, 9(1), doi: https://doi.org/ 10.1146/annurev-statistics-042720-024040 (2022)
[41] IBM Quantum Platform, *supra* note 6.
[42] Qiskit GitHub, *Qiskit Community*, https://github.com/qiskit-community
[43] Google Quantum AI, *Cirq Research libraries and tools,* https://quantumai.google/cirq/build/ecosystem
[44] NIST, *NIST Announces First Four Quantum-Resistant Cryptographic Algorithms*, https://www.nist.gov/news-events/news/2022/07/nist-announces-first-four-quantum-resistant-cryptographic-algorithms

cases, a quantum safe encryption method can be found. We find it exemplary, that all comments on the NIST decisions are provided openly available on the NIST website.[45]

This campaign trailblazed how much expertise and time is required to evaluate quantum-related topics. While quantum computers are not stable and large enough to break RSA with implementations of Shor's algorithm yet, the concept of "harvest now, decrypt later" – a mechanism of scraping data today to run it past quantum computers in the future – still puts today's data at risk. IBM has started to encrypt its own technology, such as the non-quantum z16 mainframe, using a post-quantum safe algorithm.[46] This is interesting because IBM is also a strong quantum service provider and therefore other less quantum-ready industries may like to follow their lead.

4. Quantum Networks Today

Quantum networks combine quantum computers, quantum algorithms, and the principles of quantum cryptography. The aim is to connect nodes between classical parties and quantum backends to enable a quantum-hybrid exchange between existing and emerging infrastructures. The European Union's Quantum Flagship is a major player in building long-distance quantum networks.[47] The ingredients for such networks include i) small low-cost photonic clients, ii) larger quantum processing nodes, iii) heralding integration hubs, and iv) quantum repeaters to bridge long distances. Overarching software and control layers must be able to address and coordinate all devices. One flagpole project is the *Quantum Internet Alliance.*[48] Stephanie Wehner, director of the initiative, identifies three key R&D questions

[45] NIST Information Technology Laboratory Computer Security Resource Center, *Post-Quantum Cryptography*, https://csrc.nist.gov/Projects/post-quantum-cryptography/selected-algorithms-2022
[46] BM Research Blog, *IBM bringing organizations along quantum-safe journey*, https://research.ibm.com/blog/quantum-safe-roadmap
[47] European Commission, *Quantum Technologies Flagship | Shaping Europe's digital future*, https://digital-strategy.ec.europa.eu/en/policies/quantum-technologies-flagship
[48] Quantum Internet Alliance, https://quantuminternetalliance.org/

which are currently investigated globally: i) long distance, ii) secure functionality and iii) accessibility.[49]

The European efforts to build a Quantum Communication Infrastructure (= EuroQCI) have reached the stage of including satellites. China underlines similar ambitions to "[combine] high orbit satellites and [ones] in low Earth orbit." In 2021, China demonstrated the first integrated space-to-ground quantum network spanning 4,600 km over several cities.[50] These networks are possible because photons, i.e. "light particles", are quantum objects. They can bridge long distances over air, thereby sending quantum information over air.

We do not go further into detail here, but what regulators will have to face, are discrepancies between transmission of a classical data packages vs. a quantum one. Quantum states cannot be copied, which is known as the *non-cloning theorem*. Quantum states are also of much higher fidelity: It is changed by any kind of measurement and can unwillingly decohere through many kinds of environmental factors.[51] Another major obstacle is the lack of universally agreed quantum network protocols. This hampers global cooperation and interoperability. Standardization organizations such as the ETSI or IEEE show clear interest in setting technical requirements and definitions.[52,53] Inspiration could come from the widely successful Transmission Control Protocol (TCP).

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[49] Stephanie Wehner, *Quantum network technology*. Open Access Government, July pp.276-277 (2023)
[50] Yu Ao Chen et al., *An Integrated Space-to-Ground Quantum Communication Network over 4,600 Kilometres*, 589 NAT. 2020 5897841 214 (2021), https://www.nature.com/articles/s41586-020-03093-8
[51] Kozlowski, W., Wehner, S., Meter, R.V., Rijsman, B., Cacciapuoti, A.S., Caleffi, M. and Nagayama, *Architectural Principles for a Quantum Internet*. IETF. Available at: https://www.rfc-editor.org/rfc/rfc9340.html#name-inadequacy-of-direct-transm (2023)
[52] ETSI, *Quantum - Safe Cryptography, Computing Cryptography*, https://www.etsi.org/technologies/quantum-safe-cryptography
[53] IEEE Communications Society, *Quantum Communications and Networking: Series 1,* https://www.comsoc.org/publications/magazines/ieee-network/cfp/quantum-communications-and-networking-series-1

5. Quantum Sensing Today

Quantum metrology and quantum sensing are often used interchangeably. In essence, the former involves the preparation of quantum states to *attain improved measurements* of natural quantities, the latter category focusses on the *development of quantum sensors*. Quantum sensing offers a wide palette of devices: atomic magnetometers, interferometers, gravitational wave detectors, and imaging techniques. The aim is to enable more precise, sensitive data collection. Application areas of near-field and long-range quantum sensing include navigation, telecommunication, resource exploration, or warfare.

Older 1G quantum metrology devices, such as magnetometers (SQUIDs), quantum timekeepers (atomic clocks) and interferometers have benefitted humanity drastically.[54,55] In the military, 2G QT might shift nuances toward risks, e.g., quantum inertial navigation systems for non-GPS reliant navigation or miniature antennas disrupt principles of stealth operation.[56,57] Newer technologies may therefore need closer guards during research and later in the field. Ideally, they should get globally authorized.

In 2023, the Nobel Prize in Chemistry was awarded for the discovery and synthesis of quantum dots. Quantum dots are clusters of a few hundred atoms whose defined size and composition give them "quantized" properties. This enables their use as quantum sensors: Quantum-dot based thermometers, quantum dot radiation detectors and quantum dot photosensors are hot topics of research.[58]

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[54] Clarke & John, *The Ubiquitous SQUID: History and Applications*, Volume 63, BULL. AM. PHYS. SOC., http://meetings.aps.org/link/BAPS.2018.MAR.L32.2 (2018)
[55] Alexandra Waldherr, *Miniaturwelt | IX | Heise Magazine*, IX SPECIAL, pp.146, https://www.heise.de/select/ix/2020/13/2002807430460773157 (2020)
[56] Daniel Choi, *Quantum Technology and the Military-Revolution or Hype?: The Impact of Emerging Quantum Technologies on Future Warfare*, EXPED. WITH MCUP (2023)
[57] MAJ René G. Berendsen, *The Weaponization of Quantum Mechanics: Quantum Technology in Future Warfare* (2019)
[58] Scientific Background & Nobel Prize, *Scientific Background to the Nobel Prize in Chemistry 2023 QUANTUM DOTS – SEEDS OF NANOSCIENCE The Nobel Committee for Chemistry*, (2023)

Quantum dots are even investigated in clinical trials: Injections against retinal degeneration have produced first-in human safety data, published in 2021.[59] A not-yet recruiting study will further investigate the effect of quantum dots in retinitis pigmentosa further.[60,61] Older medical technologies, such as 1G MRI and PET machines, can also be upgraded into 2G technologies. Entanglement physicists are now studying the information that comes with photons out of PET scanners.[62,63] If the two emitted 511 keV photons are entangled, new scanners could elucidate these entanglement properties and provide better insights into the photons' environment of origin, which is the tumor tissue of interest.

QTs like these will be hard to benchmark against quantum computer. The reason we mention them is that a "quantum technology" can hide and be truly beyond plain eyesight (in the most literal sense of the word). However, there is no one straightforward definition summarizing all of them.

6. Quantum Simulation Today

Quantum simulation reproduces system behavior on controllable devices. This makes complex dynamics accessible to researchers and provides interesting for many-body physics, low-temperature physics, and condensed matter physics. What should be noted, is that contrasting use of the term "quantum simulator" exists between the quantum computing community (= classical backend that simulates the behavior of a quantum computer) and the physics community (= experimental setups, that enable simulations not possible on classical

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[59] Timothy L. Jackson et al., *Intravitreal Quantum Dots for Retinitis Pigmentosa: A First-in-Human Safety Study*, 16 NANOMEDICINE (LOND). 617, https://pubmed.ncbi.nlm.nih.gov/33739144/ (2021)
[60] ClinicalTrials.gov, *Study Record*, https://clinicaltrials.gov/study/NCT05841862?cond=quantum dots&rank=1
[61] We might want to ask what does "quantum" (dots) do in patients' eyes? The injected layer of quantum dots can absorb light and electrically stimulate the damaged retina, if done correctly. In effect, quantum dots are very much indeed sensing devices that collect input and transmit output to the user.
[62] The Magazine of the Austrian Science Fund FWF, *The two-doors physicist*, https://scilog.fwf.ac.at/en/environment-and-technology/14640/the-two-doors-physicist
[63] Moskal, P., Dulski, K., Chug, N., Curceanu, C., Czerwiński, E., Dadgar, M., Gajewski, J., Gajos, A., Grudzień, G., Hiesmayr, B.C., Kacprzak, K., Kapłon, Ł., Karimi, H., Klimaszewski, K., Korcyl, G., Kowalski, P., Kozik, T., Krawczyk, N., Krzemień, W. and Kubicz, E. *Positronium imaging with the novel multiphoton PET scanner* Science Advances, 7(42). doi:https://doi.org/10.1126/sciadv.abh4394 (2021)

computers). In chemistry, quantum simulation on quantum computers is currently limited to small molecules, or to the decomposition of a larger molecule into computable pieces. Larger scaffolds can be modeled with the highly specific active site of an enzyme being formulated using an effective Hamiltonian (= "energy function").[64] The localization of electrons in a molecule, namely the electronic structure, is a key starting point for quantum simulations. Understanding electronic properties drastically improves our understanding of molecules.

Materials can also be modeled. Crystalline structures break down into repeating units, calculated on quantum computers or simulators, and then extrapolated back to the whole material's behavior.[65] It also works the other way around: Understand a material in detail can enable new computation. NIST built a quantum computer out of a single-plane beryllium crystal,[66] the first execution of Shor's algorithm was achieved using nuclear spins of carbon and fluorine atoms in a chemical molecule.[67] What we can take away from this is that the field of QT&E is not a closed, nor encapsulated topic. "Quantum biology" studies whether life builds onto quantum effects, e.g. proton tunnelling in enzymatic catalysis,[68] or endonucleases executing quantum random walks.[69] The Posner molecule is investigated for its role in neuronal processing, and recently, for its suitability to build room-temperature qubits.[70,71]

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[64] He Ma, Marco Govoni & Giulia Galli, *Quantum Simulations of Materials on Near-Term Quantum Computers*, 6 NPJ COMPUT. MATER. (2020).
[65] Chatterjee, B., Lévêque, C., Jörg Schmiedmayer & Axel U. J. Lode, *Detecting One-Dimensional Dipolar Bosonic Cystal Orders via Full Distribution Functions*. Physical Review Letters, doi: https://journals.aps.org/prl/abstract/10.1103/PhysRevLett.125.093602 (2020).
[66] American Physical Society, *Quantum Simulator Crystal*, https://www.aps.org/about/physics-images/simulatorcrys.cfm
[67] Vandersypen, L.M.K., Steffen, M., Breyta, G., Yannoni, C.S., Sherwood, M.H. and Chuang, I.L. *Experimental realization of Shor's quantum factoring algorithm using nuclear magnetic resonance.* Nature, 414(6866), pp.883–887. Available at: https://www.nature.com/articles/414883a.pdf
[68] Judith P. Klinman & Amnon Kohen, *Hydrogen Tunneling Links Protein Dynamics to Enzyme Catalysis*, Annual review of biochemistry, 82(1), doi: https://www.annualreviews.org/doi/10.1146/annurev-biochem-051710-133623 (2013).
[69] Mario D'Acunto, *Quantum Computation by Biological Systems*, IEEE TRANS. MOL. BIOL. MULTI-SCALE COMMUN. (2023).
[70] Shivang Agarwal et al., *The Biological Qubit: Calcium Phosphate Dimers, Not Trimers*, 14 J. PHYS. CHEM. LETT. 2518, https://pubs.acs.org/doi/abs/10.1021/acs.jpclett.2c03945 (2023).
[71] Shivang Agarwal et al., *The Dynamical Ensemble of the Posner Molecule Is Not Symmetric*, 12 J. PHYS. CHEM. LETT. 10372, https://pubs.acs.org/doi/abs/10.1021/acs.jpclett.1c02796 (2021).

B. From AI and Bioscience to Quantum Technologies

One way of understanding the current moment of quantum developments is that they are at a similar place as recombinant DNA had been when the Asilomar Conference was held, or AI when the Dartmouth Summer Research Project on Artificial Intelligence (DSRPAI) occurred – at the ripe moment for a thorough regulatory approach. The Asilomar Conference of 1975, prompted in part by the work of Paul Berg at Stanford, reached agreement that in the field of recombinant DNA the "proper response to new scientific knowledge was to develop guidelines on how to regulate it."[72,73] By contrast, the Dartmouth Summer Research Project, while bringing together researchers that would shape the field of AI for years to come, "failed to agree on standard methods for the field, people came and went as they pleased."[74]

Quantum technologies are in similar early-stage dynamics as those two technologies in the past. The 2G QT efforts are moving rapidly towards real-world applications and, comparable to the pre-Kefauver drug era, many promises float around in currently unregulated space. How correct are such claims, how effective is a novel technology in real-world application? How comprehensible are claims to the general population? Who is the consumer and how to protect him/her? Regulators are tasked with shielding citizens from misinformation and safeguarding against misuse.

Specifically, they are prompted with the following questions: How safe are quantum technologies? Which harms could they cause? Which learnings and analogies can we build from? In the next sections of this paper, we discuss questions like these.

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[72] Organizing Committee for the International Conference on Recombinant DNA Molecules, documented in the C. Everett Koop Papers, *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, https://profiles.nlm.nih.gov/spotlight/qq/catalog/nlm:nlmuid-101584930X515-doc

[73] Paul Berg, *Asilomar 1975: DNA Modification Secured*, 455 NAT. 2008 4557211 290 (2008), https://www.nature.com/articles/455290a

[74] Rockwell Anyoha for Harvard Science in the News, *The History of Artificial Intelligence*, https://sitn.hms.harvard.edu/flash/2017/history-artificial-intelligence/

III. What Risks do Quantum Technologies Pose that Should Worry Society and its Regulators

A. Race dynamics, asymmetric advantages and the quantum dominance

Like artificial intelligence, we are at risk of entering an *international race dynamic* with quantum computing. In such dynamics, rival powers strive to establish dominance in the field. In the context of quantum, for economic blocks like the U.S. or E.U., losing the quantum race to China might mean choosing a wrong quantum computing hardware or networking protocol standard. Wrong in the sense of a standard that won't gain sufficient international traction to become the dominant interoperability standard. Therefore, collecting feedback from the active community is what we will introduce as crucial in Phase IV later.

Ethics are often the casualty of race dynamics of this kind, for several reasons. First, race dynamics typically involve significant secrecy. It is often important for each side to hide their position in the race and how far they are from the finishing line as a way of avoiding the competitor overcoming their lead. While each side may have intermural ethical review, the siloing of information and the requirement that all ethical review occurs from within the institution diminishes the ethical scrutiny of the endeavor. There is a risk that the only ones raising ethical concerns will be those who are already mission-aligned, and even in the best-case scenario, those doing intramural siloed secret ethical review will represent less diverse a set of viewpoints than those on the outside.

Second, race dynamics have a way of downplaying the role of ethics. When race *dominance becomes an existential need*, and losing the race an *existential threat*, it is much easier to *sideline ethical concerns*. However bad it would be for the ethical concerns to manifest, the thinking goes, it would be so much worse to lose this race. For that reason, any

attempts to address identified ethical issues would slow down the path to dominance and must be put aside for the greater good.

Finally, race dynamics enable one to construct the opponent in a way that justifies overcoming ethical quandaries: "Do you think our opponent cares about these questions of human dignity you have raised?" The end result is that both sides move to an equilibrium of very loose ethical review in anticipation of their opponent doing the same.

Once in a race dynamic, it is hard to get out of one. What is needed is credible commitments from both sides to slow down their work or to adopt similar ethical rules. Germline gene editing represents a partial success story of avoiding or slowing down a race dynamic. When it was revealed that Dr. He Jiankui had engaged in germline gene editing in China as to target HIV susceptibility, there was a large amount of condemnation in professional groups and an examination by various countries about whether such research would be illegal in their territory and a move to shore up self-regulatory moratoria as well as legal prohibitions.[75] We can only speculate on what features of this story prompted this response, but there are a few that stuck out: i) the gene editing incident was *widely reported* and *comprehensible* (at least to some extent) for the general public, ii) there were already legal and non-legal *restrictions in place* among countries and scientific groups, such that it was more about "completing" or "supplementing a patchwork of existing prohibitions" than starting afresh, iii) the revelation was about a *non-state actor* who could (rightly or wrongly) be dismissed as a "rouge actor" rather than representing a concerted scientific enterprise or a state, iv) at the time of the revelation of the work it was *not the case that there were major commercial interests* invested in the technology.

[75] Henry T. Greely, *CRISPR People – The Science and Ethics of Editing Humans* (2021).

We highlight these features because it seems to us many of them may already be missing for QT. Much of the work is secret, there is strong commercial interest and investments, and large companies more than state actors are leading the change.

B. Encryption and Decryption as an Arms Race

Another problem in the quantum space is that at the national level, countries likely have an interest not only in developing quantum capabilities, but in asymmetrically doing so. In terms of benefits for national security, a country's interest lies not just in developing QT but in achieving dominance in a way to overshadow rivals. Consider encryption. The goal is not merely to be able to break preexisting encryption and develop new forms of it, but to maintain that capacity and deny it to one's rival. In this regard, a tempting analogy is the nuclear arms race – where one end goal might have been to have nuclear weapons and deny all rivals from doing so.

Historically, dominance gave way to balance of power. We saw several nuclear nations retaliate against a first mover such that first mover advantage was crushed by assured risk of mutual destruction. On one hand, the fact that the steps from one of aggression to mutually assured destruction is much longer in the quantum than in the nuclear space should give us some reassurance – an attack on encryption does not immediately lead to missiles fires and lives lost. On the other hand, quantum aggressions could be much harder to detect, and more subtle in response, which may diminish the incentive for precaution. It becomes intriguing to believe in first "tiny", "undetected" strikes.

C. Quantum Terrorism

With the anthrax bioterrorism attacks in 2001, it became evident that small systems can be powerful weapons.[76] Elucidating the origin of the miniaturized attacks would have

[76] Centers for Disease Control and Prevention, *Anthrax, The Threat*, https://www.cdc.gov/anthrax/bioterrorism/threat.html

failed without big efforts to advance the field of genetic testing and open the new branch of microbial forensics. Is terrorism with quantum technology an underestimated topic too?

Nanotechnology and nanofabrication are not necessarily the same as quantum technology. QTs often require stable shielding from environmental effects, resulting in large devices. However, QT can be expected to include nanotechnology and medical devices. This brings rise to two critical points: i) systems built on quantum effects work on inherently fragile states, making them *prone to attacks*, and ii) the smaller systems and attacks get, the *harder identification of their origin* becomes.

To date, data privacy in an age where Shor's algorithm is a reality and may soon be executable on larger hardware, is a widely discussed topic. Quantum key distribution (QKD) offers an exact solution, in that it makes eavesdroppers show up in the results of the protocol, like fingerprinted into the end measurements. Therefore, it seems to be a solution to switch away from RSA encryption, which can be broken by Shor's algorithm, onto post-quantum safe encryption and quantum protocols. However, are with these terroristic attacks mitigated?

Attacks on stealing encrypted data are often imagined to concern single persons and to be executed by single attackers. This draws a wrong image: Especially terroristic attacks target large systems and are coordinated within organizations. First efforts to systematically analyze the fragility of a quantum internet are being taken.[77] Group operability has been shown to influence quantum system much stealthier – and to derail the system much more dramatically on the long run – than a single attacker could do.[78] We have to change our thinking away from single attacker and single point of failure.

[77] Takahiko Satoh et al. *Attacking the Quantum Internet* (2021).
[78] N. F. Johnson, F. J. Gómez-Ruiz, F. J. Rodríguez, and L. Quiroga, *Quantum Terrorism: Collective Vulnerability of Global Quantum Systems* (2019).

Especially a future quantum internet, a large system with multiple nodes holding fragile quantum systems, offers many points for attack. Even without any terroristic intent, fragility in one embedded quantum system can cause widespread failure in the network. In the field of medicine, such cascades failing patients at the wrong time would lead to fatal outcomes. In the future, apart from protecting against *terroristic attacks from the outside*, *educated correct handling from the inside* will be equally important to ensure save and stable operation of quantum systems.

Near the end of 2023, Europol released an observational report on law enforcement for 2G quantum technologies.[79] They provide the beautiful counterexample that while quantum decryption poses a threat, "quantum guessing" provides opportunity for law enforcement (to crack passwords much faster in investigations). A second positive example is quantum for "digital forensics". Specific software or hardware can be circumvented to attain required to aid judicative decisions. Europol gives five concluding recommendations: i) to observe quantum trends, ii) to build up knowledge and start experimenting, iii) to foster research and R&D projects, iv) to assess the impact of quantum technology on fundamental rights, and v) to review any organization's transition plans. Overall, *fundamental education* and *preparedness* are key to identifying and counteracting quantum terroristic attacks.

In the next parts, we propose a phased approach to prepare, educate on and regulate QT loosely inspired by the way how FDA and the drug development field have structured clinical trial processes. Parallels show that this is the moment to consider an FDA-like approach for QT.

[79] Europol Innovation Lab, *An Observatory Report: The Second Quantum Revolution – The impact of quantum computing and quantum technologies on law enforcement* (2023) https://www.europol.europa.eu/cms/sites/default/files/documents/Europol_Innovation_Lab_Observatory_Report%20-%20The%20Second%20Quantum%20Revolution.pdf

IV. The *Clinical Trial* Structure: FDA History

After visiting the QT landscape and emerging regulatory questions, in the following paragraphs we summarize FDA history to later connect QT with the already established regulatory framework.

A. Towards safety, efficacy and clinical phases

The FDA history started with a single chemist in the Department of Agriculture in 1862. The agency as we now know it today, began to take shape in 1906 with the passage of the Federal Food and Drugs Act.[80] In 1937, a disaster of mass-poisoning[81] struck the United States and policymakers were forced to recalibrate policy. In 1938, the powerful Food, Drug and Cosmetic Act (FDCA) was passed to mitigate similar risks in the future. Products became for the first time evaluated for *safety*. The FDCA granted FDA more weight and authority to ensure proper and safe manufacturing of drugs.[82]

Congress instructed FDA to consider *efficacy* as well. With the Kefauver-Harris Amendment of 1962,[83] lawmakers responded to the thalidomide scandal.[84] The Kefauver-Harris Amendment authorized FDA to demand clinical data proving drugs both, *safe* as well as *effective*, prior to market authorization. Pre-1962 drugs were reevaluated on more than 16,000 therapeutic claims in the DESI program.[85] The long-standing gold standard was set to be the statistically significant, placebo-controlled, double-blinded trials that had to

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[80] FDA History Office, *FDA's Origin*, https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/fdas-origin

[81] The antibiotic sulfanilamide was impurely manufactured, leading to >100 deaths, killing >30 children.

[82] Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 ANN. INTERN. MED. 456 (1995)

[83] Jeremy A. Greene & Scott H. Podolsky, *Reform, Regulation, and Pharmaceuticals — The Kefauver–Harris Amendments at 50*, 16 N ENGL J MED. (2012) PMC: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4101807/

[84] FDA, *Milestones in U.S. Food and Drug Law*, https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law

[85] National Academy of Sciences, *Organized Collections: The Drug Efficacy Study of the National Research Council's Division of Medical Sciences 1966-1969*, https://www.nasonline.org/about-nas/history/archives/collections/des-1966-1969-1.html

demonstrate a clinical benefit. This "ideal" trial was envisioned to be preceded by smaller stepping stones: *A phased structure emerged*.[86,87]

B. International Harmonization

This phased structure for pharmaceutical development spread worldwide. Currently, FDA considers a preclinical phase (*Phase 0*), clinical trials (*Phase I – Phase III*), and post-approval pharmacovigilance practice (*Phase IV*). This structure is applied across regulators and industry around the globe. Moreover, stakeholders came together to establish the *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use* (ICH). The ICH adopted and coordinates upon this phased approach. They apply the phased thinking to release globally accepted and enforced technical documents and guidelines. [88,89] There is effort to work with each other, instead of racing against each other.

C. Binding Law Requires Entry Into a Database

Beyond the four-phase approach, the other key to pharmaceutical policymaking concerns registration. Under Section 113 of the 1997 Food and Drug Administration Modernization Act (FDMA),[90] a database system (website: clinicaltrials.gov) was opened, which would later become a globally used (or replicated) registration procedure. Impactfully, Section 113 of the FDMA made *registration of any clinical trial mandatory*. Trials monitored by FDA are implicitly covered, other areas of the world successively established equivalent

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[86] Jeremy A. Greene & Scott H. Podolsky, *supra* note 83.
[87] Suzanne White Junod & William Thomas Beaver, *FDA and Clinical Drug Trials: A Short History*, www.fda.gov
[88] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), *Official Webpage: ICH Guidelines*, https://www.ich.org/page/ich-guidelines
[89] In 1990, regulatory bodies from the U.S., Europe and Japan founded the ICH. The ICH as International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, has coordinated a CTD (= Common Technical Document) format, this schematic is used by industry to file for market authorization in an organized manner worldwide. Additionally, the ICH releases Q, S, E, M guidance documents. Respectively, focus is set on quality, safety, efficacy and multidisciplinary aspects. The guidelines that are compounded into law per member state.
[90] Food and Drug Administration, *Food and Drug Administration Modernization Act of 1997 (FDMA)*, UNITED STATES CONGR. 2295 (1997), https://www.govinfo.gov/content/pkg/PLAW-105publ115/pdf/PLAW-105publ115.pdf

systems.[91] This registration requirement was buttressed in 2005 by the International Committee of Medical Journal Editors, which made trial registration a condition for publication.[92] We emphasize this because we will argue below for a similar registration requirement for QT: We recommend a *mandatory database* to be one top priority of early QT regulatory action.

Clinical trials are now *consultable* in public databases. Regulation occurs per *phase*. The goal of each phase is to show that benefits outweigh risks. Phase I and Phase II trials are termed *exploratory phases*, starting in a small group of participants, and in a highly controlled environment. With each phase a growing number of participants is recruited to assimilate the real-world target population more closely and provide for the study of subgroups. Phase III concludes as a strong *confirmatory phase*. Phase III has to produce a data package of *clinically relevance* and *statistically significance* for regulators to grant market authorization for a novel drug. Post-authorization Phase IV studies collect refined data in the real-world setting, and are accompanied by pharmacovigilance monitoring practices.

[91] For example, the EU equivalent has been the CTR (Clinical Trials Register). Since January 2023, search for clinical trials and their related information and updates was merged into the CTIS (Clinical Trial Information System). The systems can be accessed here: https://www.clinicaltrialsregister.eu/, https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en

[92] U.S. National Library of Medicine, *History, Policies, and Laws - ClinicalTrials.gov*, https://classic.clinicaltrials.gov/ct2/about-site/history

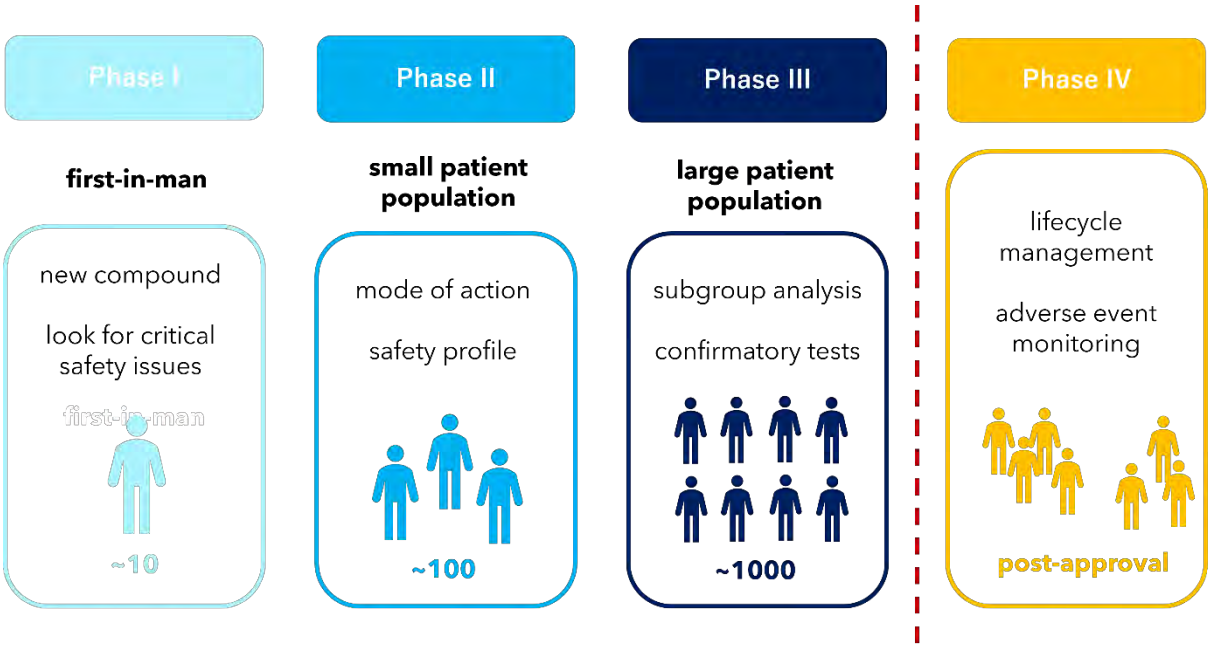

Figure 3: **Schematic of the classical four pharmaceutical phases**. The aim is to achieve high efficacy with minimal safety concerns. In words, the compartmentalization can be described as "scale-up from healthy volunteers → to real patients → to large patient group" (increasing number of people per pictogram). The *theoretical* aspect of a drug is understanding its mode-of-action. The *experimental* aspect is to find the best administration regime which holds stable under real-world circumstances. Phase III challenges both aspects harshly in the large Phase III confirmatory study. The Phase III findings are summarized in a data package for regulators, and later published as *Summary of Product Characteristics*, SmPC. After market approval and market entry (red dotted line), pharmacovigilance practice ensures safe introduction to the real-world environment.

Figure 4: **Schematic of the four *Quantum Trial* phases.** The classical four pharmaceutical phases (Figure 3) can be mapped into an equivalent schematic for the quantum technology (QT) domain. The goal is to achieve high levels of technical innovation (= "efficacy") with minimal unresolved ethical and legal concerns (= "safety"). A phased scale-up from "single experiment → to interdisciplinary replication → to real-world application" is naturally described by quantum developments.

The *theoretical* aspect is to formulate the mathematical and quantum physical framework. The *experimental* aspect is to design stable applications, that are useful for real-world users. A Phase III Quantum Trial should challenge the complete understanding on both through interdisciplinary investigations and confirmatory problem sets. Findings could be summarized as *Summary of Quantum Characteristics*, SmQC, and submitted for regulatory market authorization assessment. After the regulatory check (R.C., red line), the SmQC should be released to the public for comments in Phase IV. Educators foster idea transfer and regulatory audits accompany the Phase IV product's lifecycle.

V. The *Quantum Trial* Structure: An FDA for Quantum

While recognizing that the four pharmaceutical phases are only an analogy to what could be aspired for quantum, we describe an assimilated four-phased review process for quantum technology in the remainder of the paper. For present purposes, we refer to "the regulator" rather generically. We show how drafting along parallels to FDA and the drug development industry keeps *efficacy* and *safety* as core values in focus, while streamlining the designing of a new regulatory process to a well-established one.

The Common Divisor

Analogies of drug development can be applied to quantum development because both technologies undergo R&D which naturally proceeds in stages, or phases. These phases are well-defined for drugs. For QT the terminology to introduce is: At the start, both technologies start in laboratories under controlled conditions (= *Phase I*). After these controlled laboratory tests, they undergo a proof-of-principle validation in real patients, "patients" in a QT sense of the true problem class (= *Phase II*). Next, a benefit on real-world devices and problem sets has to be confirmed (= *Phase III*). Regulatory assessment follows. The lifecycle of a new technology begins with market authorization and entry. Responses form the active community accumulate, the QT gets updated if necessary and educational outreach should be fostered drastically (= *Phase IV*).

Translating drug phases to quantum, we are in the position to ask whether the FDA framework can be evolved one step further. In our eyes, standardized documentation formats per *Quantum Trial* phase would add a benefit. We conceived four proper documentation formats that are time-efficient for the author, understandable for the actors of the adjacent phase, and feasible for educational purposes. Specifically, we suggest a technical one-pager (to accompany *Phase I*), an ethical checklist (*Phase II*), a diverse product assessment portfolio, SmQC (*Phase III*), and regularly updated failure reports (*Phase IV*).

Regulatory thought experiments

To illustrate how a regulator might guide QT through the phases, in the following we will provide two thought examples to help visualize each stage and respective regulatory questions.

The first thought experiment concerns a quantum algorithm: Say, we want to take in weather parameters and output an optimal flight trajectory to minimize climate effects.[93,94] It has been proposed that changing the height or local path of a plane can drastically decrease contrail formation.[95] By this negative environmental contribution of planes can be mitigated. In 2021, DLR and EUROCONTROL executed a first-ever operational contrail avoidance trial with remarkable success, by adjusting plane trajectories over the northwest of Europe.[96,97,98] One crucial problem remains: Calculating such optimal routes on many parameters (temperature, weather patterns, sun position, other aircrafts) is hard to do in a fast, classically efficient way. A future quantum algorithm may combine two aspects currently appraised as quantum computing strengths, i) solving optimization problems and ii) processing simultaneously on many input parameters. Regulators will account also for a risk scenario.[99]

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[93] Parameterized circuits are a standard approach in quantum optimization designs, additionally, a strength of quantum computers is their proposed possibility to process on a high number of parameters in parallelized fashion.

[94] It should be noted that "parameterized" in a quantum circuit refers to different parameters than the input. Analogous to classical machine learning, parameters in a quantum circuit are tunable values refined via training, while input parameters need to be mapped to appropriate quantum languages, quantum states on which to compute on.

[95] The authors thank Lorenz Hübel for discussion on this idea and hinting at the DLR study.

[96] DLR Deutsches Zentrum für Luft und Raumfahrt – Institut für Physik der Atmosphäre, *Vermeidung langlebiger Kondensstreifen erfolgreich nachgewiesen*, https://www.dlr.de/pa/desktopdefault.aspx/tabid-2342/6725_read-89226/

[97] In the last year, while 3.5% of anthropogenic climate impact[156] is to be attributed to aviation, it has been found that up to two thirds of this contribution are not caused by CO_2 emissions but by more tangible non-CO_2 effects. The most impactful effect being the formation of persistent contrails and cirrus clouds, that drastically impact reflectivity of incident sunlight.

[98] Robert Sausen et al., Can we successfully avoid persistent contrails by smart altitude adjustments of flights in the real world? METEROL. Z. (CONTRIB. ATM. SCI.) (2023) https://elib.dlr.de/200025/1/Sausen%202023%20metz__Can_we_successfully_avoid_persistent_contrails_by_small_altitude_adjustments_of_flights_in_the_real_world_102979.pdf

[99] Such a quantum algorithm would catapult aerospace industry and environmental activism into a new era. But what if somebody would start to adopt this algorithm and optimize missile trajectories? A regulator will have to think of exactly these dual use 'edge' cases.

The second regulatory thought experiment is about hardware. We follow the SQUID, a technology which is already widely implemented and has followed "quantum phases" silently since the 1910s. The SQUID device is a magnetometer (or a quantum sensor) that can measure tiny magnetic fluxes. It will be our second regulatory thought example. At the hand of the SQUID's historical path, we showcase how the *Quantum Trial* framework maps almost perfectly to a natural QT development trajectory that has been running since more than a century. The reader can from this build an intuition of why and how a *Quantum Trial* thinking is practical and truly applicable.

1. Phase I: It Starts with an Experiment, or a Theoretical Idea

Pharmaceutical template: In the pharmaceutical process, regulated trials begin when an idea moves from preclinical testing to *first-in-human* testing. The focus is on proving safety in humans and titrating the effective dose regimen.[100] Similarly, there are *first-in-quantum* moments. Moments, when small *experiments* inspire serious development of a quantum technology, or when a *novel idea* in a theorist's mind becomes pursued with determination. Novel in the sense of original, unseen before.

RQT (Responsible quantum technology) equivalent: Two aspects ultimately merge: All quantum innovation requires a *theoretical description* ("mathematical proof-of-concept") and *successful experimental implementation* ("empirical proof-of-concept"). This translates roughly to a "proof-of-safety" and a "proof-of-efficacy". In Phase I, technologies do not meet both criteria. For regulators, "first-in-quantum" studies can therefore be understood as mainly academic QT research, on either the theoretical or the experimental branch. Many

[100] FDA, *Step 3: Clinical Research (Phase I)*, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

publications under Nature Scientific Reports' category *Quantum Physics*[101] illustrate such beginnings, where a novel "pre-quantum" idea is first developed into a fully discussed topic.

Quantum Trial Phase I document: Phase I *Quantum Trials* should complete with a technical description of a novel proof-of-concept. Unanimously, this is today accomplished by scientific publication. To mainstream knowledge transfer effectively, a binding document summarizing Phase I results could be adopted, e.g., in the form of a comprehensive technical one-pager (ideally in machine-readable format for automatic database entry). The one-pager should be a time-efficient piece of writing explaining i) the idea, ii) implementation and iii) outcome in technical language, essentially a tutorial for colleagues to replicate or built upon the exact setup. The difference to a standard publication today would shorter, instructive writing style and summary of core terms and formula with detailed explanation per term.

If we adopt pre-registration requirements for *Quantum Trials*, we could request technical one-pagers at the close of any submitted project.[102] Thereby we would ensured that negative attempts are equally voiced, documented, and valued.

What is the role of the regulator in Phase I? Regulators at this stage would strive to capture all available technical one-pagers but leave enough room for early technologies to evolve. From the regulator's perspective, a horizon-scanning program would be ideal, to capture the (common) motives of latest developments in their rawest form.[103] If claims from either branch – *theoretical* or *experimental* – become too disruptive (compare nuclear bombs, genetic engineering of stem cells), international communication should be evoked. A quick decision on whether to prohibit the research or how to support such critical edges should be decided on global quorum.

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[101] Nature, *Quantum physics articles within Scientific Reports*, https://www.nature.com/subjects/quantum-physics/srep

[102] Similar to how clinical trials have to report outcomes, regardless of scientific publications on (good) results.

[103] Greely, H.T. Governing emerging technologies—looking forward with horizon scanning and looking back with technology audits. *GPPG* **2**, 266–282 (2022). https://doi.org/10.1007/s43508-022-00045-y

Regulatory thought experiments in Phase I

On a quantum algorithmic idea: The flight trajectory optimization algorithm begins in the head of a quantum information scientists. Her/his novel idea is to take a standard flight path input and evolve upon it parameters (such as weather patterns) to bring the qubit into an output state that represents the optimal flight trajectories with high probability. The idea gets "first-in-quantum" executed on short flight trajectories and small parameter sets, under the ideal lab conditions (*Phase I*). The results of the test cases get published, on the regulator's desk a technical one-pager arrives. It depicts a quantum circuit schematic and explains how to translate real-world parameters into quantum language. The regulator assesses mathematical and technical soundness behind protocol and implementation: How are the qubits defined, how the algorithmic logic? Are both well-defined? What are expected inputs and outputs? How stable is the approach and the system? Are other *Phase I* trials investigating similar ideas and can she/he facilitate exchange between these groups?

On a quantum sensor: In a laboratory, an experimental observation occurs that electrical resistance in a mercury thread vanishes while cooling the wire down to temperatures close near absolute zero. The experimental result gets published in a scientific journal. The quantum regulator is confronted with discovery of a novel phenomenon. A few years later, another group follows up with a theoretical interpretation and attributes the observation to a quantum effect. Namely, at low temperatures, electrons seem to move through wires in a paired, condensed fashion, producing the observed charge transfer at no electrical resistance. The quantum regulator recognized how now experimental and theoretical branch are merging.

Aware of the novel potential, the regulator organizes *labsite training*:[104] The superconducting phenomenon is new to the regulatory map, therefore it is good to prepare and educate the regulatory team in advance.

In summary: Regulatory agencies act as a hub to oversee all experimental and theoretical efforts in Phase I. If both branches – experimental and theoretical proof – are fulfilled, this marks the entry of a technology into Phase II. In the registry database, regulators flag any QT that moves to Phase II.

2. Phase II: Experiment and Theory Merge

Pharmaceutical template: In Phase II, the transition of pharmaceutical trials moves from "healthy volunteers" to "patients". The step from "perfect laboratory model" towards "real-world problem sets" is taken with the goal to refine research questions, and to develop methods for large Phase III investigations.[105] Quantum approaches where both i) experimental evidence and ii) a mathematical, theoretical proof are met, can equally advance into Phase II.

The RQT (Responsible Quantum Technology) equivalent: Applied research motivates to identify effective application of QT: Is the quantum technology capable of solving the intended problem? Does the technology provide useful solutions? Which steps are critical in transforming the fundamental findings from Phase I into a successful application? The goal of

[104] "Labsite training" or later "labsite regulation" might be a novel concept to play with for the hard-to-educate field of quantum technology, especially as a quantum-iterate workforce is only in the educational pipeline. A regulator regularly visits and works with a Phase I, Phase II or Phase IV team (Phase III being left out for integrity of unbiased market entry assessment) to hands-on experience expert handling, failure modes, pressing issues, correct vocabulary usage.

[105] FDA, *Step 3: Clinical Research (Phase II)*, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

Phase II is to make certain that QT can realistically match a problem. Ethically, the inventor's intentions in conjunction with the real problem dynamics gets thoroughly explored.

Quantum Trial Phase II document: We suggest that the original innovators are given the first say in listing ethical concerns and compiling a *profile of intended use* – the *ethical checklist*. Both, benefits and potential for harm, must be taken into account. Particularly high-profile values to ascertain are i) *material and energy* requirements (environment, access restrictions), ii) *complexity* of the technology (educational aspect), iii) *destructive potential* (military, cybersecurity), iv) *high cost* (societal, market imbalance), v) *low cost* (inclusivity for the public vs. accessibility for malicious act), vi) possible impact on *food and water*, and vii) possible impact on *human health*. These categories are in alignment with the United Nations Sustainable Development Goals.

What is the role of the regulator in Phase II? For standardized implementation and time-efficient completion (as laboratory hours are preferred over administrative work by scientists), regulatory authorities can provide an online risk assessment questionnaire.[106] Ideally, the resulting ethical checklist would be attached to all future publications as supporting information.[107] After Phase II, a promising idea can be taken up by many less experienced players and societal impact seems likely. The original intentions should stably accompany the idea through future actions. Best ethics are ensured when a technology is used as intended at all stages of development. The checklist acts as a translator to protect scientists' and regulators' original intentions, raise awareness of scenarios to avoid, and correctly transfer knowledge to educators, the public and legislative teams.

[106] Inspiration on a risk based monitoring scoring tool could be taken from the RBM Score Calculator, developed by the Swiss Clinical Trial Organisation, used by sponsors and sponsor-investigators planning and monitoring clinical trials in Europe. Automatic compilation of a formatted reports concludes the online questionnaire. Accessible under: https://www.sctoplatforms.ch/en/tools/risk-based-monitoring-score-calculator-31.html and https://ctu-bern.shinyapps.io/rbmc/

[107] See Phase I: Regulators should flag technologies entering Phase II in a registry database. If this is reliably done, publishers may get pinged by the database and automatically query for the ethical checklists.

Regulatory thought experiments in Phase II

On a quantum algorithmic idea: Academically, the *Phase I* test problems were "self-defined" by the research team. Now, in *Phase II*, the test problems are defined by "real-world" data. The quantum optimization algorithm is tested on larger problem sets, where all parameters of interest are included, and the output format must map to real-world plane paths. Minor tinkering of the program should cease and stable runtimes are the goal. The researchers declare the intended use case, design and implementation, the *ethical checklist*.

The regulator takes the "outside view of the public". How will people interact with this QT? What problem do they want solved, and what kind of solution benefits the end user? What solution benefits society at large? From this perspective, the regulator can ask for additional assessments. Optimization comes often with the risk of heavily focusing on one aspect, while a balanced approach may provide the best solution.[108] For example here, the regulator requests a renewed algorithmic implementation that combines contrail formation with CO_2 emission optimization. The research group adjusts the algorithm to minimize on both, CO_2 and non-CO_2, climate effects.

Crucially, the regulator pinpoints risk scenarios: What use cases would harm society at large? The regulator remarks that instead of plane trajectories and emissions, missile trajectories could be optimized. She/he contacts legislators to prohibit and safeguard against this specific use case in a pre-mortem analysis.[109] If the decision falls that the benefit of large-scale climate protection outweighs this risk, itself the optimization algorithm may remain in development.

[108] For example, CO_2 emissions may increase through adjusted flight trajectories and these last longer in the atmosphere than temporary non-CO_2 contrails. Therefore, both dimensions should be optimized.
[109] In the binding database, such classified or prohibited use cases could be clearly highlighted and communicated in streamlined fashion between all stakeholders and to the public.

On a quantum sensor: The regulatory team completes their labsite training on superconductivity. As expected, Phase II registrations for superconducting technologies spike in rather accelerated fashion: One research team shows how when a loop of superconducting material is interrupted by two Josephson junctions – two thin insulating layers – a periodic relationship between the current in the loop and the magnetic flux[110] flowing through the loop, can be plotted. Tiniest changes in magnetic fields can be reproducibly measured. This implementation demonstrates successful characteristics of a highly innovative sensor type.

The ethical checklist for the sensor handed to regulators: Real benefits for material science and energy research, for medicine, for astronomy are noted. Concerning to the regulator are stated material requirements: Liquid helium for cooling is necessary, a resource not available in every part of the world, with limits to Earth's general reserves. Moreover, recycling of helium is little incentivized in the U.S., so most helium is lost to the atmosphere and dissipates into space. The raw material is primarily mined only together with natural gas.[111]

From other QTs, the regulator has experience with the problem of extensive cooling requirements (e.g., helium-3 cools the "refrigerator" around many quantum computers). Actively, she/he reaches out to legislators for incentivizing the recycling, responsible use, and long-term availability of liquid helium.

Summarizing, the goal of Phase II is to align quantum implementation and problem, thereby identifying risks or bottlenecks at an early stage. The inventor's intent is recorded in an ethical one-pager and the regulator guards these ethical core values in Phase III and Phase IV.

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[110] An important physical concept being magnetic flux quantization, with the flux quantum as $\Phi_0 = \frac{h}{2e}$.

[111] United States Geological Survey, *Helium 2021, Mineral Commodity Summary 2022*, (2022) https://pubs.usgs.gov/periodicals/mcs2022/mcs2022-helium.pdf

3. Phase III: Interdisciplinary Investigations of the Application

Pharmaceutical template: Phase III is much less academic in nature and runs with larger industrial scales and economic incentives. Often termed *pivotal phase* or *confirmatory phase*, Phase III relies on heavy data collection and large recruitments. The medication in its final form is administered over long duration to patient groups and analyzed for efficacy and (rare) side effects. Findings are statistically consolidated in a holistic data package for regulatory review and market authorization.[112] Integral to market authorization is the submission of a Summary of Product Characteristics (SmPC, EMA)[113] or the United States Prescribing Information (USPI, FDA).[114]

The RQT equivalent: QTs in their final stage of development should undergo a similar holistic, interdisciplinary assessment. A multidisciplinary team of investigators would allow to arrive at a data package that consolidates subproblems, edge cases, and unusual setups. We envision an independent group consisting of third-party auditors, industry experts and academic scientists with no conflict of interest to conduct such Phase III investigations. Important questions to clear are: Is the technology stable? Can boundary conditions be accurately predicted? Can a wider range of problems ("patient groups") benefit from this QT than originally thought?

In the process, the multidisciplinary team identifies good and bad practices. Valuable lessons are recorded that may have been overlooked in the previous "idealistic" Phase I and Phase II studies. The QT owner themselves should be held accountable to revoke or validate any previously published claims on the QT's capability. Exemplarily, if the technology owner

[112] FDA, *Step 3: Clinical Research (Phase III)*, https://www.fda.gov/patients/drug-development-process/step-3-clinical-research
[113] European Commission, *Notice to Applicants: A Guideline on Summary of Product Characteristics (SmPC)*, https://health.ec.europa.eu/system/files/2016-11/smpc_guideline_rev2_en_0.pdf
[114] FDA, *Prescribing Information Resources For Industry*, https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/prescribing-information-resources

claimed that an algorithm could revolutionize medicine, material research and finance, now in Phase III, they should provide small-scale show-and-tell sandbox examples per claimed area.

Quantum Trial Phase III document: A document similar to the SmPC, with an enhanced touch towards a practical manual, could conclude Phase III *Quantum Trials*. We call this document the SmQC (= Summary of Quantum Characteristics). At a minimum, the SmQC should include information on i) the technology owner, ii) a description of the technology, iii) references to the utilized quantum effect(s) used/why it is claimed to be a quantum technology, iv) use cases, v) prohibited use cases, vi) reference to the ethical checklist, vii) operating instructions, viii) a portfolio of use-case examples and viii) best practice commentary.

For point viii) – the use-case example portfolio – the assessment team works further with educators and the QT holder. Together, they collect beta-testing user stories and create easy-to-follow tutorials. Playfulness of education should not be forgotten just because "quantum" precedes the word "technology". Failures modes will be identified while doing so. These should boldly be highlighted in the SmQC later. In the best case scenario, both together would form a rich collection of materials of high technical quality and of high educational value.[115] We advocate for objective RQT benchmarks test results to be included in SmQCs. However, it will require deep technical ingenuity to find and agree on appropriate ones in the quantum field. Benchmark tests for some QTs are emerging, e.g. atomic clock designs by the Naval Research Laboratory, or quantum computers with the *Quantum Volume*.[116,117,118]

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[115] A counterexample of what not to do, is to copy only one and the same tutorial all over. Not long ago, the main quantum computation computing platforms exclusively used all the travelling salesman problem to introduce optimization algorithms, even though this class of algorithms was claimed to help not only help logistics, but also machine learning, bioinformatics, physics and chemistry too. If you claim it, provide a simple educational example per field.

[116] Thai M. Hoang et al., *Micro Mercury Trapped Ion Clock Prototypes with 10^{-14} Frequency Stability in 1-Liter Packages*, 13 SCI. REPORTS 2023 131 1 (2023), https://www.nature.com/articles/s41598-023-36411-x

[117] Miller et al., *supra* note 32.

[118] Elijah Pelofske, Andreas Bartschi & Stephan Eidenbenz, *Quantum Volume in Practice: What Users Can Expect From NISQ Devices*, 3 IEEE TRANS. QUANTUM ENG. (2022)

What is the role of the regulator in Phase III? We leave open for now, whether the regulator will instate an assessment team or whether the technology owner has certain rights to assemble an interdisciplinary team by himself, as is common in the pharmaceutical domain. In both cases, the selected experts shall analyze both dimensions of i) *stability* (= variations in implementation of the original problem) and ii) *scalability* (= implementation on variations of the original problem).

A major hurdle we want to highlight for Phase III is that at such a late stage (= close to production license and market approval), the technology owner is most often an economic entity under economic pressure. The quest for open educational material and benchmarks, often stands diametrically opposed to economic and commercial interests. The Phase III regulator – our proposed *FDA for Quantum* – could acts as the counterweight to commercial pressures. The end of Phase III contains the regulatory check (R.C.), marking the final release from development towards entry into the product's lifecycle and Phase IV.

Regulatory thought experiments in Phase III

On a quantum algorithmic idea: The flight trajectory optimization algorithm has finalized Phase II with an approved ethical checklist and was purchased by a non-profit environmental agency. The environmental agency as new *technology owner*, together with the regulator, instates an assessment team of multidisciplinary experts to create a robust SmQC. The regulatory agency stresses the importance of the SmQC, as it provides the main manual for the future user community. The regulators themselves will go through submitted tutorials to verify clear communication.

The first tests assessors supervise concern *stability*. The algorithm is implemented on various hardware architectures, and the results of each execution are validated, documented and compared with the other hardware architectures. Phase II *implementation* questions become Phase III *application* questions: Are long flight optimizations crossing the equator

forecastable? Do seasonal changes in weather patterns produce a difference in circuit execution? Which units of data input are required, Fahrenheit vs. Celsius? A strong Phase I and Phase II provide a good baseline to leave little questions for Phase III.

To empower responsible use, the technology owner sets up small-scale sandbox environments, tutorials for users to test and understand under which conditions the algorithm runs stable. Citizens users may be recruited to play with the algorithm on old weather patterns and itinerary data. Failure modes and error messages are collected. Best practices become defined for the SmQC.

The assessors next assess *scalability*. Can ship routes be optimized for minimal ecosystem disruption? Can bee flight be studied, or traffic congestions resolved? Not all tests on scalability produce useful solutions. Failures become precisely defined: When were input question wrongly formulated? Which data cannot be inputs to the algorithm? Which problems are not tractable by this optimization approach?

Eventually, the regulator receives the whole data package from the technology owner. Separately, the authority runs a classified assessment on missile trajectory optimization. This use case was previously classified "forbidden" during Phase II. The main responsibility of the regulator(s), the *FDA for Quantum* ("FQA"), lies in assessing all data and deciding whether the collected knowledge and the conceptualized use cases encapsule enough technical and educational material for i) inclusive, responsive and reflective legal actions and ii) for public release and communications. Having decided that the QT will benefit a fair, lawful and ethical society, the regulator signs of the final regulatory (R.C.) check.

<u>On a quantum sensor:</u> In the magnetometer example, several companies simultaneously submit magnetometer application designs for Phase III regulatory review and market authorization. To avoid running short on staff, various regulators collaborate and exchange information.

One technology holder submits a Phase III data package describing three distinct medial use cases, the measuring heart signals (= magnetocardiogram MCG), brain signals (= magnetoencephalogram MEG) and iron levels in kidney and liver (= biomagnetometer). Our quantum regulators ask for a split into more targeted SmQCs: Technical designs and instructions should be defined specifically for each of these sensible use cases. Three separate SmQCs arrive back at the regulatory agency, the sensor designs are approved. For approval as clinical diagnostic devices, the regulators hand the data packages further to the FDA.

Another technology holders submit data packages on setting the magnetometer up in less critical settings than medicine. For example, to set the SQUID up as readout assemblies in telescopes. Here, the requirement for educational materials is lower: The quantum sensor will be handled by technicians and physicists, the application range is highly specific and less critical than the medical field. We bring these two examples to showcase how may adapt decisions on a case-to-case (or application-to-application) basis. *It is a regulator's task to regulate, but not to overregulate*.

In summary: A regulator in Phase III decides the authorization of a technology for each application. She/he sets requirements for educational materials. In general, the preparation of tutorials and benchmarks should be an integral step among Phase III investigations. During the final regulatory check (R.C.) regulators assess the data package and approve the consolidated SmQC. Positive decisions are entered into the mandatory database[119] and the product begins its lifecycle in Phase IV.

[119] The regulators should have a consolidated database already set from earlier trial phases. Otherwise, at least at this stage a database on assessed and approved quantum technologies should be instated. Ideally, after the R.C. any international databases present should be harmonized and updated with the decision. If applicable legislative guidelines, laws or a certification mark could be linked.

4. Phase IV: Real-World Application and Continuous Improvement

Pharmaceutical template: Once the newly approved medication hits the market, the environment is very different. The circumstances for a marketed, globally used technology are in stark contrast to the ever controlled, almost sterile, trials before. For drugs, rare side effects often surface only at this stage with more people taking a drug, in an inhomogeneous worldwide population. At the same time, compliance becomes much less supervised, and inter-individual variety emerges in how people around the world handle a technology. To address this shift in the risk/benefit picture, post-market surveillance and vigilance databases are used to capture the real-world dynamics and ensure safety control.

The RQT (Responsible Quantum Technology) equivalent: There should be a similar mechanism to safeguard QT against unexpected risks on the global market. In our eyes, the best way to strike "*quantum vigilance*" upon market entry is to build educational curricula and foster a *quantum-literate society*. Customers interact with QT in a more dynamic way than they do with pharmaceuticals. A drug to swallow is in most cases a passive system. However, a quantum sensor is an open system that reads data in from the environment and out to the user. Quantum programmers will suggest parameter changes or version updates.

The more educated regulators and the general public become on expected "quantum behavior", the faster failure modes will be noticed and reported. Less "try-and-error" fidgeting takes place, leading to more efficient processes and safer environments. Education increases users' integrity and encourages a "try-to-improve" spirit.

Quantum Trial Phase IV document: End users and customers should be given an active role in Phase IV vigilance processes. Most of the time users identify "side effects" and skilled, quantum-savvy, users are likely to pursue innovative ideas and improvement. Thus, if the technology holder is open to take failure reports – and national security and intellectual property provisions permit – the QT can advance iteratively from feedback and suggestions.

The reporting channel for feedback should be *a public and moderated service*. Failure reports should be openly available and updated regularly.[120]

What is the role of the regulator in Phase IV? Today already, the educated community becomes the central paradigm of Phase IV: With quantum programming frameworks, we see the efforts being carried by global communities. For quantum hardware, accessibility shifts a bit. Single users can globally request cloud access but not bring the resources per se to their home. The regulator can catalyze the exchange between public suggestions and industry, coordinating idea influx from the community and the integration of ideas by the technology owner. In addition, regulators catalyze discussion between countries and support multinational educational initiatives, scientific cooperation and harmonized legislation.[121,122,123,124]

Regulatory thought experiments in Phase IV

On a quantum algorithmic idea: Regarding our quantum aviation optimization algorithm, as soon as it enters the market, a regulator monitors the first few months closely. She/he engages aviation providers to submit erroneous calculations and technical failure reports that occur during executions of the new QT application. Lessons are learned from this error collection: The regulator joins forces with the technology holder to verify that every application instance meets the Phase II ethical checklist. The regulator also collaborates with

[120] Inspiration from the pharmaceutical industry could be the PADER (U.S.), PBRER (ICH) or PSUR Periodic Safety Update Reports structure as required and well-explained by the EMA, visit: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/periodic-safety-update-reports-psurs

[121] A successfully established example of a Phase IV technology would be *Micius*, a quantum communication space satellite that has executed quantum key distribution between China and Austria since 2016. The international collaboration led to a successful press conference, with the data transfer secured by exactly this secure, quantum-encrypted link. Educational materials were developed, and international collaboration fostered. Lessons learned from this early satellite link have been incorporated into the European Quantum Communication Infrastructure (EuroQCI), coordinated by the European Commission. This shows that legislators are following the field with interest and take supportive steps.

[122] Institute for Quantum Optics and Quantum Information, Satellite Based Quantum Communication, https://www.iqoqi-vienna.at/de/research/zeilinger-group/satellite-based-quantum-communication

[123] European Space Agency, *QUESS eoPortal Satellite Missions Catalogue*, https://www.eoportal.org/satellite-missions/quess

[124] European Commission, *The European Quantum Communication Infrastructure (EuroQCI) Initiative,* https://digital-strategy.ec.europa.eu/en/policies/european-quantum-communication-infrastructure-euroqci

educators and fosters the use of SmQC sandbox tutorials in the classroom and QT&E academic programs.

On a quantum sensor: For the magnetometer example, Phase IV entry lies in the past rather than in the future. As mentioned, we followed the historic development of the ubiquitous SQUID quantum magnetometer. Today, it is one of the most used quantum technological devices.

Recapping Phase I to Phase IV: The discovery of vanishing electrical resistance was originally made by Heike Kamerlingh Omnes Leiden in 1911 (*Phase I, experimental branch*), the mathematical description was added in 1957 by Bardeen, Cooper and Schrieffer with their publication on Cooper pairs (*Phase I, theoretical branch*). The implementation towards becoming a concrete quantum sensing device (*Phase II*) was realized at Ford Research Labs in 1964, where concepts of superconductivity, magnetic flux quantization and Josephson junctions were combined into the first DC SQUID ever developed. Today, the SQUID is used to diagnose epilepsy, it sits at the tip of atomic force microscopes, is used in mineral exploration, telescopes and even as qubits (*Phase III*, P*hase IV*).[125,126] The quantum computing company D-Wave uses RF SQUIDs as superconducting flux qubit design in their quantum annealer hardware architecture.[127]

The SQUID's past exemplifies the close correlation between natural stages taken by a quantum innovation and our proposed, concretely formalized phases. We see the wide impact – from astrophysics, to mineral exploration, to medicine – one quantum innovation can have.

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[125] Clarke & John, *supra* note 54.
[126] Heather McCarrick et al., *The Simons Observatory Microwave SQUID Multiplexing Detector Module Design*, 922 ASTROPHYS. J. 38 (2021), https://iopscience.iop.org/article/10.3847/1538-4357/ac2232
[127] DWave, *Coupled rf-SQUID Qubits, Annealing Implementation and Controls D-Wave System Documentation*, https://docs.dwavesys.com/docs/latest/c_qpu_annealing.html?_gl=1*sm0lxn*_ga*OTA0NjM1NDEzLjE3MDAzOTQ0MjY.*_ga_DXNKH9HE3W*MTcwMDM5NDQyNi4xLjEuMTcwMDM5NDQ5MS42MC4wLjA.#hardware-coupled-rf-squid-qubits

However, most people have never noticed the SQUID, even in the scientific and technical domain. What the SQUID could have benefitted from are stronger educational materials.

While no regulator has guarded the SQUID's development, the specific material and supercooling requirements created and automatic burden against misuse. Mostly advances and came out for the SQUID. This showcases that a *graded approach of criticality* may be helpful for QT. While for pharmaceuticals, every drug may be potentially toxic, in the quantum regime, this will not always be the case. A regulatory *registry* should be *sorted by criticality.*

To summarize, we explored whether the current set up pharmaceutical regulation – three phases that precede approval followed by a fourth post-approval monitoring stage – can serve as practicable analogy, reinterpreting a familiar structure for the new class of 2G QT.

We view our contribution as starting the basic conversation. There are many details to work out. Towards building an overarching authority, questions in need for answers are: How close should quantum regulators adopt FDA working principles? Which rights will they have in withdrawing existing technologies to the market? How can fair competition and collaboration be positively influenced globally, instead of weakened by new national regulatory requirements?

These are many important implementation questions which, in the interest of modesty as to our own expertise, we are not opining on. Concrete open questions are how an "FDA for Quantum" should be structured as an agency in the U.S. (or in other countries), how it would hire reviewers, how applications or fees should be best handled, how could international collaboration between regulators in different countries or internationally work? And how can QT scientists, engineers and education be supported and funded?[128]

[128] The Stanford Quantum Incubator (to be inagurated in October 2024) aims at facilitating this goal. Stanford Law School, *Stanford Quantum Incubator, Stanford Center for Responsible Quantum Technology,* https://law.stanford.edu/stanford-center-for-responsible-quantum-technology/projects/stanford-quantum-incubator/

VI. Open Questions

In the previous parts, we have shared preliminary ideas about how regulators could approach the review of quantum technologies and targeted analogies to the FDA's approach. Many questions remain. In this section we self-consciously flag some of these points, while recognizing that our list is far from exhaustive. We also acknowledge and address arguments against the approach we have proposed.

Open Question 1: How can we educate regulators?

We agree with top educational institutions that the best time to establish quantum curricula was *yesterday*. Today's regulators need to be trained by and with researchers "in-the-lab". Labsite teaching is not an established practice among regulatory agencies. However, it it would allow for early horizon scanning and close networking. Being at the frontier during training, regulators would learn the appropriate vocabulary from the active community and become immersed hands-on in the most pressing and actual R&D questions. Compensation should be offered to research laboratories who take time to be part of such exchange, and they should later benefit from regulatory advice.[129]

Open Question 2: How can one specialized regulator handle the large domain variety of quantum technologies?

As the discussion above suggests, QT comes in many shapes and sizes. Probably not all personnel can be trained on all topics. One strategy to assign regulators' responsibilities would be to have one regulator getting educated for one technological device in Phase I, and her/him being later responsible for the same or similar QT. Indeed, we recommend one QT to be guided by one leading regulator through all *Quantum Trial* stages.

[129] Similar to scientific advice being granted for free (or reduced fee) to certain laboratories or small companies in the pharmaceutical sector to aid a fast and clear regulatory flow.

When it comes to cyber technologies this is very much a path not taken in the U.S. Instead of having a single cyber regulator who does everything from domain names to so-called “revenge porn”, we have a fragmented regulatory process across many federal agencies, state agencies, international bodies, and underlying common law such as tort law. It is possible that this cannot be avoided for quantum applications and technologies – that QTs designed towards drug and devices should get review by FDA, while applications to telecommunications by FCC and so on. The downside is that quantum expertise is in short supply among the workforce generally, this approach would scatter experts even further across different agencies, making staffing up difficult.

Each agency may apply distinct forms of regulatory review, looking for different things, such that the review process is not only fractured but inconsistent. It may be the solution falls somewhere in between, with a centralized coordination sitting in the White House – a sort of quantum “czar” overseeing programs in distinct aspects of the federal government. That design, though, may be unsuitable for some other countries leading in quantum science. We think this is a real problem, but one for which the optimal configuration is too soon to tell.

In the EU, a guideline to adhere to the *Quantum Trial* framework may be the path to go, nationally implemented per country with one responsible competent authority. On the contrary, a harmonized EU-wide agency could be instated. Later proved more fruitful for pharmaceuticals.

Open Question 3: Which education on QT&E is already available?

As with the question on future quantum regulators' responsibilities, similar questions stand unanswered for future educators. There are many uncertainties in how to establish educational QT&E programs. While within the physics community, we enjoy a high standard of open communication, this stands in contrast to mixed-quality media coverage and almost no educational prerequisites among citizens.

There are early K-12 programs, however, even on academic level, courses covering QT&E may be mixtures of Youtube channels and MOOCs. Quantum engineering and technology aspects in textbooks lack completely behind.[130,131,132] To cite MIT professors' on establishing a new QT&E program:[133]

"Quantum theory textbooks are predominately written by physicists and assume a great deal of physics background […]. Even more seriously, to our knowledge, no quantum engineering textbook presently exists for learning the diversity of quantum hardware."

There are first efforts to change this. In Europe, the German Stifterverband sparked a *Quantum Skills* initiative and suggested eleven points how to foster quantum skills in teacher education and respectively forward these skills to the young public.[134] All recommendations call unanimously for modernization, systematization, and lower entry barriers to high quality educational material. It is not sufficient to educate only on academic level. Educating the general user is as central for *R*QT (*responsible* quantum technology) as developing the

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[130] Asfaw et al., *supra* note 17.
[131] Artur Ekert, YouTube Channel Arthur Ekert, https://www.youtube.com/@ArturEkert/about
[132] Stifterverband, *Quantum Skills in der Lehrkräfteausbildung*, https://www.stifterverband.org/quantum-skills/curriculum-labs
[133] Asfaw et al., *supra* note 17.
[134] Stifterverband, *Position Paper: Quantum Skills*, https://www.stifterverband.org/sites/default/files/2023-10/quantum_skills_in_der_lehrkraeftebildung_empfehlungen.pdf

technology itself. Similar to AI (a field that is widely discussed but not always understood), a lack of educational transfer restricts who can regulate and what can be regulated.[135,136]

Open Question 4: What powers should be given to companies? What power should be given to users?

At the moment, companies offering quantum technology access decide the rules. For example, the recent IBM Quantum End User Agreement[137] (effective since December 2, 2023) states in one paragraph that reverse engineering or decoding of hardware is strongly forbidden. In the paragraph following directly after, the user is called, he or she "may not use [the technology] in any application or situation where failure could lead to death or serious bodily injury of any person, or to severe physical or environmental damage, such as aircraft, motor vehicles or mass transport, nuclear of chemical facilities, life support or medical equipment, or weaponry systems." We positively support that ethical principles are "entangled" thoughtfully with quantum systems. But to which degree can a user from the general public accessing the free platform be held responsible for the implications of his or her quantum computing actions? Also, can a user be expected to safeguard his or her software on a system when no full insight on the backend is allowed? Additionally, with the new update, the platform usage becomes restricted to a smaller subset of countries. Might access decision by companies lead to very poorly balanced global power dynamics?

[135] Brian Cox, *Why Quantum Theory Is So Misunderstood*, ECUR. DI WALL STREET JOURNAL, Feb. 20, 2012, https://www.wsj.com/articles/BL-SEB-69030
[136] Frank L. Smith, *Quantum Technology Hype and National Security*, 51 SECUR. DIALOGUE 499 (2020), https://journals.sagepub.com/doi/10.1177/0967010620904922
[137] IBM, *End User Agreement | IBM Quantum Platform*, https://quantum.ibm.com/terms

VII. Philosophical Frameworking: Quantum-ELSPI and RQT

The *Quantum Trials* model proposed here started as a means to classify quantum algorithms, and was developed collaboratively develop to unify the QT domain as a whole. It is based on the *Responsible Quantum Technology (RQT)* paradigm conceived at Stanford University and has been operationalized in this model. Over the past year, a group of international researchers has defined and explored the interrelated societal implications of the QT, to discuss a wider scope than a technical or an ethical perspectives alone. Legal, societal and policy implications are central pillars of the ongoing efforts. These have led to the development of foundational concepts such as Quantum-ELSPI, and the SEA framework for Responsible Quantum Innovation (RQI). The following section explains these concepts and their interrelationship.

A. Quantum-ELSPI

Just like any evolving technology such as semiconductors, AI, nano, genetics, synthetic biology, and nuclear fission & fusion, quantum has interrelated *E*thical, *L*egal, *S*ocio-economic, and *P*olicy *I*mplications. This is exemplified by the umbrella acronym Quantum-*ELSPI*.[138] A traditional ELSI approach is explicitly extended to a public policy instrument to address national and economic safety and security interests. Concerns as well as their geopolitical dimensions are included.

The Quantum-ELSPI metaparadigm signifies a set of overarching concepts for studying and communicating the development and use of 2G QT in our society. Descriptively, Quantum-ELSPI denotes research focused on the societal aspects of QT. Normatively, Quantum-ELSPI can be thought of as a metaparadigm that sets an interdisciplinary research agenda from the highest abstraction level down to an everyday workfloor practice. Similar to

[138] Mauritz Kop, *Quantum-ELSPI: A Novel Field of Research*, 2 DIGIT. SOC. 2023 22 1 (2023), https://link.springer.com/article/10.1007/s44206-023-00050-6

dialogue between physicians, statisticians and various medical experts in clinical development, ELSPI discussions provides teams with rich, interdisciplinary perspectives.

B. Responsible Quantum Technology (RQT)

*R*esponsible *Q*uantum *T*echnology (*RQT*) encompasses the development and use of QT in a way that is consistent with Quantum-ELSPI principles. Guided by the key pillars of *R*esponsible *R*esearch & *I*nnovation, four values carry particular importance: *A*nticipation, *I*nclusion, *R*eflection and *R*esponsiveness (*AIRR*).[139]

In language towards RQT:

- Anticipation translates to the public's understanding how RQT can solve problems, and furthering its development with positive excitement.
- Inclusivity describes which proportion of the public is quantum literate, has access to the technology, and is empowered to shape the future of the field. Today, inclusivity in (R)QT is non-existent for large segments of the general population or limited to industry initiatives, such as the IBM's Open Quantum Cloud.
- Reflection is understood as developers and policymakers finding a continuous cycle of improvement. Past mistakes are turned into lessons learned and corrected. This is tricky for the young field of QT, retrospective learnings have yet to be logged. Prospectively, reflexivity is possible in the form of early diligent checks of proposals and promises (see SEA TURTLE below), both on the technical and the ethical side.
- Responsiveness to RRI seeks to promote a culture of R&D that actively involves citizens. It includes a responsibility to update globally and timely on the

[139] Christopher Coenen & Armin Grunwald, *Responsible Research and Innovation (RRI) in Quantum Technology*, 19 ETHICS INF. TECHNOL. 277 (2017), https://link.springer.com/article/10.1007/s10676-017-9432-6

interpretation of what *beneficial, sustainable, inclusive*, and *socially responsible* mean to humanity. RQT action should be constantly (re-)aligned accordingly, at any current point in time, towards the common good.

C. Technological Revolutions Call for Legal Recalibration

A technological revolution necessitates the recalibration of the legal framework, and a new form of applied ethics. It requires the evolution of technology law. RQT prescribes QT to be lawful and commit to legal principles, such as the rule of proportionality and subsidiarity. Future legislation should reduce quantum-specific risks in conjunction with maximizing benefits, yet also providing legal certainty and promoting responsible quantum innovation.

RQT governance and legislation requires an intricate equilibrium between underregulation and overregulation. According to the Collingridge dilemma, there is always a trade-off whilst attempting to regulate a specific technology: Interfering with the innovation process to soon may disproportionally impede the anticipated positive innovation externalities. Acting too late generated undesired path dependencies after the emerging technology becomes locked-in.[140]

When planning their regulatory and technology governance interventions during technological revolutions, policymakers face a shortage on historical datapoints. However, given similarities to adjacent fields, policymakers can draw from the past of closely related disciplines, such as AI, nanotechnology, biotechnology – or in this publication from the pharmaceutical domain – and think beyond them. Given the fast, exponential pace of 2G QT and the market readiness of quantum-AI hybrids, we see agile, problem-based, device-based approaches to quantum governance and regulation among the best solutions.

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[140] Audley Genus & Andy Stirling, *Collingridge and the Dilemma of Control: Towards Responsible and Accountable Innovation*, 47 RES. POLICY 61 (2018).

D. SEA Principles

Our research group proposes to operationalize the RQT paradigm through the adoption of 10 Principles for Responsible Quantum Innovation, which we developed in a second study to assist in addressing currently identified and future risks, challenges, and opportunities connected with quantum technology.[141] The ten principles guide the *Quantum Trial* framework through three core functional categories: the SEA principles.

SEA is our steadfast commitment to **S**afeguarding, **E**ngaging and **A**dvancing (SEA) quantum technology, society and humankind. These principles triage our actions on whether they truly increase awareness, establish trust, and guiding QT toward beneficial societal outcomes from a pro-innovation stance.

E. SEA TURTLE: A fast checklist for concrete action

We further distilled these 10 Principles and the RQT metaparadigm down into the form of a concrete, memorable checklist. The SEA TURTLE checklist can be applied to any *Quantum Trial* in progress. In a world of mixed quality media claims, engineers and the public alike shall have a fast tool in hand to check a QT's development status. The SEA TURTLE is built for this purpose: In essence, a QT faces six core checks to be defined an i) innovative and ii) responsible quantum advancement. We packaged them into a memorable acronym (see Figure 5).

[141] Mauritz Kop, Mateo Aboy, Eline de Jong et al., *10 Principles for Responsible Quantum Innovation*, Stanford Law School 2023, https://law.stanford.edu/publications/10-principles-for-responsible-quantum-innovation/

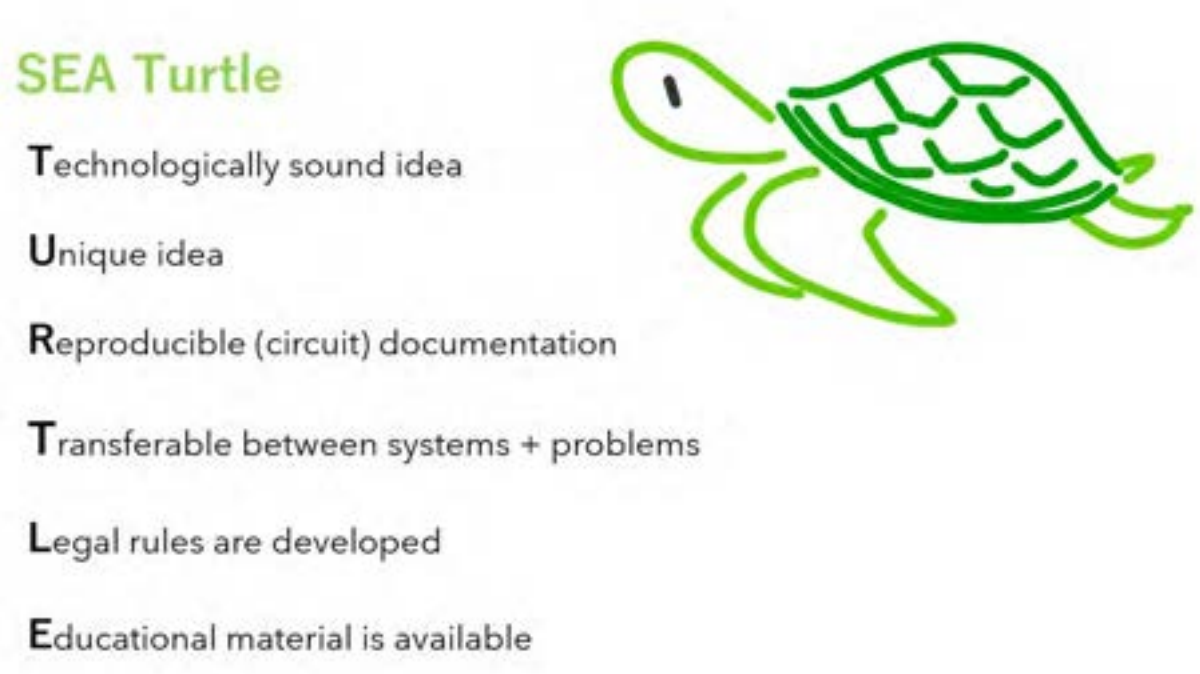

Figure 5: **The SEA TURTLE framework benchmarks a technically novel and responsible quantum technology (RQT).** While not exhaustive, it provides engineers and the public with a quick checklist that is easy to apply. The SEA TURTLE checklist may act as barometer in technical, ethical and legal conversations and support accuracy in educational transfer.

Interestingly, the SEA TURTLE acronym cannot only aid regulators and engineers with a quick assessment tool but be used as a *barometer* to elucidates which stage of development a QT resides at, which gaps are to be filled towards becoming an RQT: In the case already only first points (more technical questions) are met with *No*, the technology sits in very early stages or might be guided by a misled interpretation of "quantum". Regulatory intervention is not pressing.

If first questions can be answered with *Yes* and only later questions (more societal questions) with *No*, the quantum technology moves close to real-world applications. Ethical, educational and legal action should now definitely be discussed.

If all questions can be answered with *Yes*, both technical and societal development are in harmony. This should be the goal for any RQT.

VIII. Conclusion and Future Outlook

This article introduces novel perspectives on how to regulate QT responsibly, drawing inspiration from the pharmaceutical regulatory framework in the U.S. In particular, the four phases of clinical trials as utilized by the FDA for market approval of novel medicines, can be mapped onto four developmental phases of 2G QT. This approach provides a starting point to guide quantum developments through a structured pipeline.

We call upon the quantum physics community to critically discuss the applicability and feasibility of the proposed framework. In parallel, we invite the legislative branch to test, adopt, evaluate, and provide feedback. The eventual goal is to establish an agreed upon *ontology* of subdisciplines and topics – similar to the WHO Anatomical Therapeutic Chemical Classification (ATC)[142] – and release a set of *standard units and benchmark measurements* – similar to WHO Defined Daily Doses (DDD) – upon your feedback.[143]

We propose four core documents, one per *Quantum Trial* phase, to guide the quantum R&D process: A technical formula one-pager (*Phase I*), an ethical checklist (*Phase II*), a multidisciplinary portfolio with worked tutorials – named SmQC*,* Summary of Quantum Characteristics (*Phase III*), and an open channel for educational material and failure reporting (*Phase IV*).

While outlining this ambitious RQT roadmap, we are realistic that implementing it requires time and significant political capitol. But there is at least one piece of low-hanging fruit that would be a good regulatory first step and could be effectuated separately from the rest of the program we have outlined: *registering quantum trials*. The first crucial step to

[142] World Health Organization, *The ATC/DDD Methodology*, https://www.who.int/tools/atc-ddd-toolkit/methodology
[143] *Id.*

accomplish is to pass a legislative act which makes the registration of quantum developments mandatory, in the form of either a Presidential Executive Order or a Congressional Bill.

As briefly hinted at in Section IV, regulators do not have to set up a whole framework at once. Instead, just sparked by Section 115 in the FDCA declaring registration into a database, all of federal authorities, industry and academia could be harmonized and register clinical trials in a standardized format. We recommend building a similar database to clincialtrials.gov, e.g. quantumtrials.gov, in the next years. Required registration provides the best starting point for attaining an overview. Regulators become equipped with data to balance underregulation and overregulation, while resources and funding can be targeted.

Sequentially, the way to set up an *FDA for Quantum* requires four steps ...

i) make registration of quantum technology developments binding by law

ii) discuss and refine the *Quantum Trials* structure as international consortium

ii) incorporating an overarching agency – an "*FDA for quantum*" (FQA) – tasked with coordinating, auditing, and monitoring the *Quantum Trial* database

iv) provide targeted funding and high-quality sources to researchers and educators

These would allow active exchange and targeted pro-innovation RQT investments to agencies, researchers, industry and educators. An *FDA for Quantum* has the potential to become a respected source of knowledge similar to a Patent Office, well pre-sorted to lower educational barriers for all stakeholders. Ultimately, the U.S. could become a trailblazer in guiding QT away from possible threats and miscommunication, towards enabling researchers to develop new ideas, incentivizing industry to bring innovations to the market, and

humankind to ultimately benefit from this groundbreaking set of technologies in a responsible, equitable, and ethical manner.

Through open databases and education, we at this point in time have the power to completely change the narrative about QT around: From “incomprehensibly hard” into “the coolest devices we will ever work with.”[144]

[144] In the most literal sense, as many quantum technologies require cooling to almost absolute zero to counteract for thermal fluctuations.

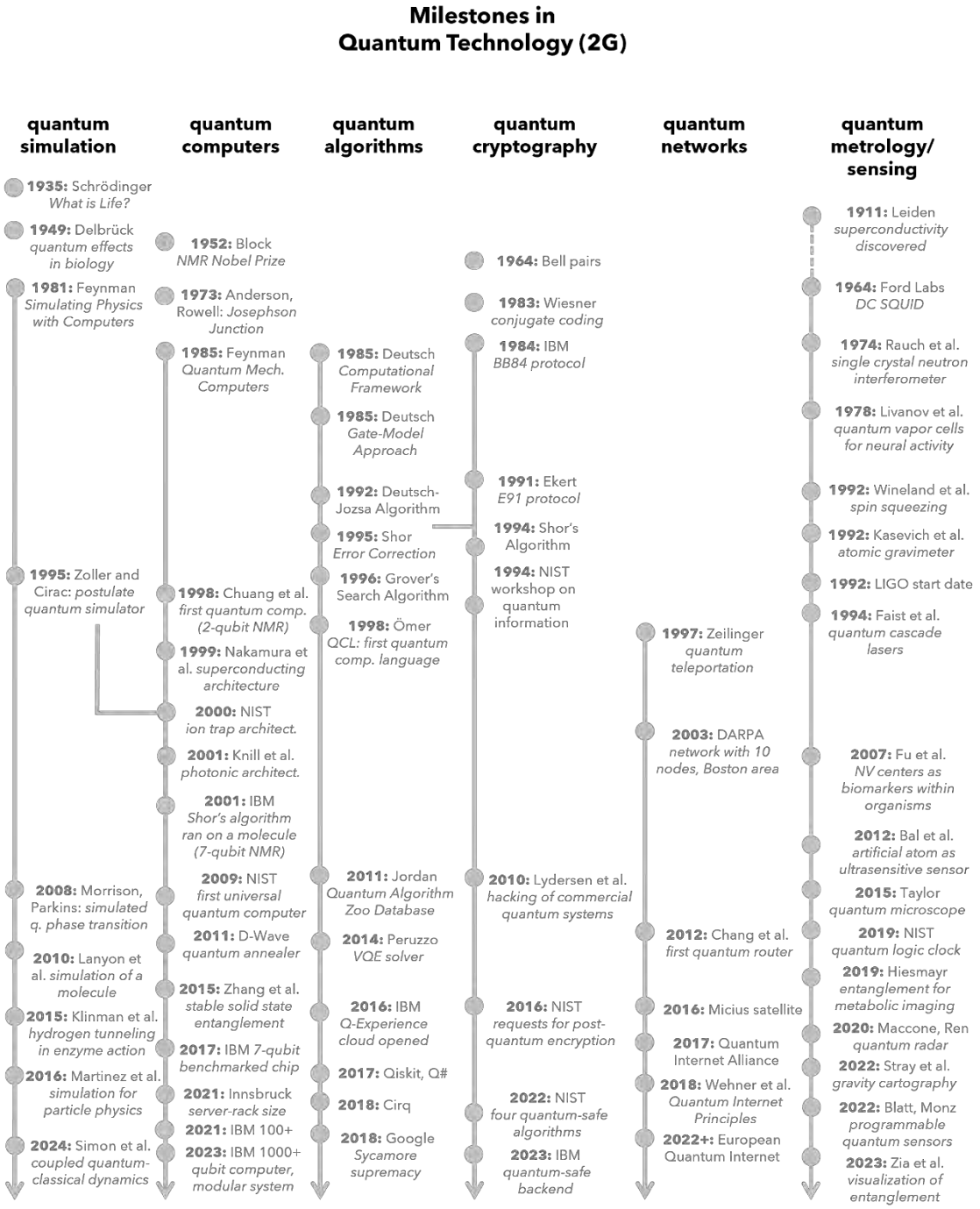

Figure 6: **Timelines of selected quantum technology (QT) developments.** We grouped the field into six topics (branches). Interdisciplinary collaboration among researchers is fostering a dynamic, accelerated flow of developments. *Quantum computers* and *quantum algorithms* together with *quantum cryptography*, make up the field of what is often referred to as "quantum computing". It might be important for regulators to adapt per topic area and to understand which research has led to the current state-of-the-art.