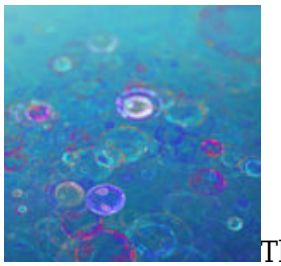
FDA Announces Total Product Life Cycle Advisory Program (TAP) Pilot

 The U.S. Food and Drug Administration's ("FDA" or "the Agency") Center for Devices and Radiological Health ("CDRH") recently announced the launch of its Total Product Life Cycle Advisory Program ("TAP") Pilot. The first phase of this voluntary initiative, called TAP Pilot Soft Launch, will be conducted during fiscal year ("FY") 2023 with enrollment beginning on January 1, 2023.

The Agency committed to establishing the TAP Pilot as part of the MDUFA V reauthorization, and the Agency's long-term vision for TAP is "to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance." As part of the TAP Pilot, the FDA will provide strategic engagement for such devices by:

- Improving participants' experiences with the FDA by providing for more timely premarket interactions
- Enhancing the experience of all participants throughout the device development and review process, including FDA staff
- Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk
- Facilitating regular and solutions-focused engagement early in device development between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers
- Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process

Read client alert **here**.

FDA Issues Final Clinical Decision Support Software Guidance

 On September 28, 2022, the U.S. Food and Drug Administration ("FDA" or "the Agency") issued its long-awaited final guidance, "Clinical Decision Support Software" (the "CDS Guidance"). The CDS Guidance follows the Agency's September 2019 draft guidance of the same name (the "Draft Guidance") and seeks to clarify several key concepts for determining whether clinical decision support ("CDS") software is a medical device.

Specifically, the CDS Guidance provides the Agency's interpretation of the four criteria established by the 21st Century Cures Act for determining whether a decision support software function is excluded from the definition of a device (i.e., is considered "Non-Device CDS"). A software function must meet all of the following four criteria to be considered Non-Device CDS:

1. Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device ("IVD") or a pattern or signal from a signal acquisition system
2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
3. Intended for the purpose of supporting or providing recommendations to a health care professional ("HCP") about prevention, diagnosis, or treatment of a disease or condition
4. Intended for the purpose of enabling such HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Software functions that *do not* meet all four criteria are considered device functions subject to FDA oversight. Notable updates to FDA's interpretation of the four criteria include the following.

Read the Goodwin insight **here**.

Visit the **Goodwin on Medtech hub** to stay informed on important developments affecting medtech innovators and investors.

Potential AI/ML Learnings to Come from FDA Public Advisory Committee Meeting on Skin Lesion Analyzer Technology in Late July

 On July 28, 2022, the U.S. Food and Drug Administration (FDA) will hold a public advisory committee meeting to discuss skin lesion analyzer (SLA) technology and its application to detecting skin cancers in various patient care settings. This meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee will focus on algorithm-based SLA devices for adjunctive detection of skin lesions, including skin cancers, and stands to provide industry another layer of thinking on FDA's perspective on artificial intelligence and machine learning (AI/ML) device technologies.

In announcing this meeting, FDA explained that in recent years it has observed an increased interest in SLA devices employing AI/ML. The agency is seeking expert input from the panel on approaches to evaluate the performance of SLA devices, which have a range of technologies and indications.

The committee will discuss and provide recommendations to FDA on: (1) the diagnosing standard, or ground truth, that should be used as a comparison for the performance of diagnostic devices, e.g., histology, consensus opinion of a panel of dermatologists, opinion of a single dermatologist, or other means; (2) acceptable sensitivity and specificity thresholds based on the target diagnosis (melanoma, basal cell carcinoma, squamous cell carcinoma) or intended user (dermatologist, primary care physician, lay user); (3) patient characteristics, including lower or higher incidence populations, that should be tested before marketing; and (4) the balance of increased access with risk mitigation measures that are appropriate when the devices are used by lay people, by populations with very high or very low incidence of melanoma, by populations with low incidence, but high mortality associated with melanoma, or by the target diagnosis/lesion type.

Additionally, on July 29, 2022, the committee will discuss the possible reclassification of two class III, PMA approved computer-aided melanoma detection devices, MelaFind (P090012) and Nevisense (P150046), both of which are intended for use on cutaneous lesions suspicious for melanoma when a dermatologist chooses to obtain additional information when considering biopsy. According to the FDA announcement, "The committee will discuss if there is sufficient information to reclassify computer-aided devices for adjunctive diagnostic information of lesions suspicious for melanoma from class III to class II, and what special controls may be appropriate to provide reasonable assurance of safety and effectiveness" if they are reclassified.

This meeting, and any actions the FDA takes as a result, could offer industry further insight into the FDA's approach to regulating AI/ML diagnostic and screening products more broadly.

The meeting will be held virtually on July 28, 2022, from 9 am to 5:45 pm ET and July 29, 2022, 9 am to 4 pm ET. Comments received on or before July 11, 2022 will be provided to the committee and the public docket will remain open for comment for FDA's consideration until August 29, 2022.

For more information see the **Meeting Notice on the Federal Register**.

Five Tips for Life Sciences Companies to Protect Their AI Technologies

 Given that artificial intelligence (AI) – historically the domain of software companies – is a new frontier for many life sciences companies, we have assembled five helpful tips to consider for protecting AI technologies:

Tip 1: Make sure you have permission to use the data

Familiarize yourself with the data privacy rules applicable to the types of data you are collecting and develop an appropriate consent form with all proper disclosures and terms.

Tip 2: Get IP assignments from everyone contributing to the AI technology

For AI technologies, the universe of contributing individuals may be broader than expected. For example, individuals that: (1) select the data to be acted on by an AI engine, (2) review the outputs of an AI engine, (3) select the algorithms used to train the AI model and tune the modeling parameters, and/or (4) write the source code to implement an AI engine.

Tip 3: Be careful when using open source software

Incorporate good hygiene around your use of open source software and implement policies and procedures to ensure that no source code is used that could jeopardize the secrecy of your proprietary code.

Tip 4: Be thoughtful about the type of legal protection you want for your technology

Consider the following factors when deciding between patent and trade secret protection: (1) likelihood of independent invention, (2) detectability of the invention, and (3) speed of innovation.

Tip 5: If you choose patent protection, employ strategies to maximize chances of success

Describe in your patent applications the AI model's performance and the improvement(s) over conventional techniques. Ideally, use statistical data such as ROC curves, measures of predictive values (PPV or NPV), confusion matrices, F1 scores, and other similar data.

Read the full insight

UK Government Announces ‘Future Fund’ Financing Package for Start-Up Technology and Life Sciences Companies


The UK Government has announced a new fund that provides financing to UK start-ups and scale-ups in the form of a convertible loan which is invested directly by the Government. For further detail on the fund please see: https://www.gov.uk/guidance/future-fund.

Read the Alert >>

COVID-19: U.S., State Governments Expand Access to Telehealth Services; Reduce Other Barriers to Care


In response to the COVID-19 pandemic, the U.S. and many state governments have taken a number of steps to expand access to telehealth services and reduce other barriers to care. Among other things, the U.S. Centers for Medicare and Medicaid Services (CMS) has eliminated a number of restrictions on the coverage of telehealth services under Medicare to enable coverage of services provided to patients, including new patients, located in their homes. Many commercial payors have also taken action to expand access to telehealth, including by eliminating co-payments for such services. Many states have temporarily waived in-state licensure requirements to enable physicians, registered nurses, licensed practical nurses, nurse practitioners, and other medical personnel licensed in any state to provide telehealth services to their residents. The Department of Health and Human Services (HHS), Office of Inspector General (OIG) announced that physicians and other practitioners will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services. The HHS Office for Civil Rights (OCR)

additionally announced that during the pandemic, it will allow healthcare providers to provide telehealth services to patients through any non-public facing communication applications such as Apple FaceTime, Facebook Messenger, Google Hangout, and Skype. Finally, the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) have both taken steps in response to the COVID-19 pandemic to remove barriers restricting patient access to controlled substances and medicines. We review these developments below.

Read the Alert >>

Developing Medical Products for Public Health Emergencies

The 2019 novel coronavirus (coined COVID-19 by the World Health Organization) is the latest in a series of public health emergencies in recent years to challenge product developers in the life sciences community. With every challenge comes an opportunity, in this case to leverage product development plans and technologies to be first-to-market with products useful in remediating some aspect of COVID-19 and its spread. Earlier this year, the U.S. Food and Drug Administration (FDA) announced its commitment to extend all available resources to help expedite the development and availability of medical countermeasures (MCMs) to prevent, treat, or diagnose COVID-19 and, in fact, issued the first emergency use authorization (EUA) shortly thereafter. For life sciences companies exploring potential opportunities to leverage their programs to help treat, detect, or address some aspect of COVID-19, a number of regulatory mechanisms may be available to facilitate and advance product development plans.

Read the Alert >>

I want to license technology out of an academic or research institution. What kind of compensation will the institution typically look to receive?

 Academic or research institutions are at the core of early-stage innovation in the life sciences and biopharmaceutical industries. In order to gain access to the intellectual property generated or owned by those institutions, institutions typically offer to grant a license to its owned intellectual property to companies. In exchange for the license, institutions will look for consideration, which comes in a variety of forms. We can break down types of typical consideration into a few categories.

1. License Issue Fee: Institutions may ask for an upfront fee for the grant of the license. This is a one-time payment paid at the signing of the license.
2. Minimum Annual Royalties/Annual License Fees: Aside from the upfront fee, many institutions will ask for an annual "maintenance" fee. These can take the form of yearly lump sum payments, but can also sometimes be called "minimum annual royalties". If these payments are considered minimum annual royalties, then the yearly fee is creditable against any royalties owed to the institution that year.
3. Royalties: Institutions may ask for a percentage of the future sales of products that incorporate the intellectual property licensed. This comes in the form of on-going royalty payments. Typically, for most institutions, these are in the single-digits, but depend on the scope and breadth of the license.
4. Development/Commercial Milestones: Institutions may ask for lump sum payments based on the achievement of certain developmental or commercial milestones by the company. For example, if a product that incorporates the intellectual property licensed from the institution receives FDA approval, the institution may ask for a lump sum payment upon such achievement.
5. Sublicensing Income: Institutions like to ask for what we call "sublicense income". Through sublicense income, the institution is entitled to a percentage of the consideration the company receives from a sublicensee, if the company sublicenses the institutions intellectual property to a third party. The percentage varies and usually decreases over time, but is typically in the single-digits to low double-digits.
6. Patent Costs: If the company is taking an exclusive license, the institution will typically want the company to cover the costs of prosecuting any patents being licensed, those both already incurred and to be incurred in the future. In exchange, typically the company will have input in the future prosecution of the patents.
7. Equity: Depending on the relationship of the institution and the company, some institutions may request equity in the company in exchange for the license grant.

The amount and frequency of the above categories will vary from license to license, and will depend on the scope and breadth of the license (e.g., exclusive v. non-exclusive, limited geography v. worldwide, narrow field v. all fields, etc.). There also may be consideration institutions will ask for, other than the above. We recommend connecting with your Goodwin licensing or commercial counsel to discuss what might be typical for the scope of license you intend to enter into.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: Trends in Biopharma

 On Wednesday, January 15, 2020, during the J.P. Morgan Healthcare conference, Goodwin and KPMG held their initial all-day Symposium at the St. Regis hotel in San Francisco. The Symposium was composed of five separate "bursts" entitled (i) New Frontiers in Digital Diagnostics and MedTech, (ii) Europe Unleashed, (iii) Knowing the Best IPO Strategy, (iv) Trends in Biopharma and (v) Mergers and Acquisitions. Stéphane Bancel, the Chief Executive Officer of Moderna Therapeutics, provided the keynote address.

Burst Four consisted of a panel entitled "*Evaluating and Partnering New Technologies and Emerging Business Models*." This panel was moderated by **Kingsley Taft** from Goodwin, **Jeffrey Stoll** from KPMG and Nicholas Pullen from Bristol-Myers Squibb. In this panel, participants provided their insights regarding active deal sectors in biotech and issues to consider with respect to deal structure.

Key takeaways from Burst Four were as follows:

1. ***Platform technology deals in areas involving gene therapy, mRNA and immuo-oncology have been active, but some concern persists that companies in certain areas are over-valued, potentially decreasing the overall number of deals that have been made.*** Although many areas of biotech have actively been generating deals, the number large deals announced in the run-up to JP Morgan appeared to be less than in the prior year. The panelists suggested that the decreased number of deals may be a function of the high valuations that have been placed on biotech companies, noting the premium acquisition price that Roche paid for Spark as an example.
2. ***Given the complexities associated with certain platform technologies, such as gene therapy, many pharma partners prefer partnering deals as opposed to outright acquisitions for platform companies.*** Panelists suggested that pharma companies are more likely to favor a partnership structure over an acquisition structure when it comes to early-stage platform technologies in biotechnology. The reason for this is that the platform technology is likely to need a great deal of additional investment in numerous areas, including manufacturing, before the emergence of a product candidate that the pharma company is willing to develop on its own. In addition, it is very difficult for a pharma company to put a valuation on an early-platform company, but things become easier when the platform actually starts to generate potentially marketable products.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: New Frontiers in Digital Diagnostics and MedTech

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Burst One consisted of three parts. Roger Cohen from Goodwin provided an overview of the current state of the healthcare sector and regulations. During this session, Roger provided an overview of the FDA's definition of a medical device subject to FDA regulation, highlighting whether digital technologies would be encompassed within such definition. In addition, Roger reviewed other key federal and state laws of importance to companies involved in the digital healthcare space – including privacy laws such as HIPPA – and state laws regarding the corporate practice of medicine.

The second part of Burst One was a panel entitled "*New Frontiers in MedTech Space on the Global Stage: What are the Challenges in IP, Regulatory and Commercial*?" This panel was moderated by **Kristin Ciriello Pothier** from KPMG, and consisted of **Nicholas Mitrokostas** from Goodwin, Stefan Scherer from GlaxoSmithKline, Joseph Zaccaria from TrialSpark and Reena L. Pande from AbleTo. In this panel, participants provided their perspectives regarding the numerous challenges associated with bringing new medical technology to market, including as it relates to intellectual property, regulatory approvals, reimbursement and commercialization.

The final part of Burst One was a panel entitled "*Issues Facing Therapeutic Companies Using ML and AI in Drug Discovery Methods*." This panel was moderated by **Danielle Lauzon** from Goodwin and consisted of David Berry from Flagship Pioneering, and Dan Housman from Graticule and Courage Therapeutics. In this panel, participants provided their insights regarding how artificial intelligence, or AI, and machine learning, or ML, is used in the drug development process, and debated what type of input data is necessary for AI and ML to be truly useful in the drug development process.

Key takeaways from Burst One were as follows:

1. ***MedTech, digital diagnostic and health IT companies should seek guidance from experienced counsel as early on in the process as possible as laws and regulations are numerous and complicated.*** Various panel members noted that one of the biggest mistakes

that companies in the evolving medtech, digital diagnostics and health IT spaces make is failure to consider the numerous, complicated laws and regulations that may apply to their technologies. Therefore, they highly recommended obtaining experienced lawyers early in the company lifecycle to avoid potential missteps. For example, determining whether certain medical software will be regulated as a medical device by the FDA is very fact intensive and requires input from an experienced regulatory specialist as there are dire consequences for making the wrong determination. In addition, it is important to note that these laws and regulations are constantly evolving, therefore, something that may be permissible today may not be permissible in the future. Experienced counsel can keep you up-to-date on pending developments that might affect your company.

2. ***In many areas, the law has not kept pace with the speed of technological innovations; therefore, a great deal of gray space remains.*** Panelists noted that legal issues facing companies in rapidly-evolving sectors may not have a clear answer as the law has not kept pace with the speed of technological innovations. For example, in patent law, folks have had to consider whether a computer should be deemed the investor of the output from certain AI processes.
3. ***In order for new technologies in areas such as medtech, healthcare IT and digital diagnostics to become successful on a large scale, there is a need to balance the innovative mindset with the entrenched mindset and there must be an openness to collaboration both internally and externally.*** Many panelists cautioned that in order for new innovations in medtech, digital diagnostics and healthcare IT to be accepted by the current healthcare system, it will require a great deal of cooperation between the innovators and the entrenched players. Therefore, panelists advised that companies developing new technologies in these areas should seek to involve more entrenched players into their decision-making and development process as early as possible, and to seek returns on a smaller scale before seeking returns on a larger scale in order to build credibility.
4. ***AI has a great deal of promise in drug development, but questions remain regarding (i) how to obtain a sufficient amount of data for useful predictions, and (ii) the quality of the data that is used to arrive at predictions.*** Panelists noted that AI can be used throughout the drug development lifecycle, from assisting with target selection to helping predict the patient population that is most likely to respond to a product candidate. However, a panelist cautioned that the hype associated with AI should be toned down, as AI has yet to provide many of the promised benefits. Furthermore, there are many differing positions regarding the type of quality of data needed for AI to be truly useful in the drug development process.