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DIGITAL HEALTH PRIVACY: FROM APPS TO AI

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Digital Health Privacy: From Apps to AI

- Topics to Be Discussed Today Include:
 - Origins of OCR and the FTC Privacy Regulations
 - Gray Areas of Privacy Regulations
 - Business Associate Status and Consequences
 - OCR, HIPAA, and COVID-19 Guidance
 - Activity Trackers, Wellness Programs and Virtual Assistants
 - AI in Healthcare
 - Enforcement and Guidance Documents by OCR and the FTC
 - The Internet of Things
 - Practical Application Scenarios and Key Takeaways

The Technologies Are New, the Laws ... Not So Much

- When the Health Insurance Portability and Accountability Act was enacted in 1996, there were no smartphones, no mobile apps, and no cloud computing
 - HIPAA Privacy Rule became effective April 14, 2003
 - HIPAA Security Rule became effective April 21, 2005
 - Compliance date of HIPAA Omnibus Final Rule, incorporating HITECH Act changes: September 23, 2013
- In recent years regulators and digital health companies have had to interpret existing laws to fit this new landscape of:
 - Healthcare mobile apps
 - Wearable devices
 - Cloud-hosting services
 - Personal health records

Privacy by Design

- For companies venturing into the digital health space, privacy and security are critical issues that must be addressed from Day One
 - For startups, questions about privacy and security will be among the first that get asked by customers and potential acquirers
 - The due diligence process will show when a company scrambled to improve privacy and security immediately prior to potential acquisition
 - For established companies venturing into digital health, a stumble in the digital privacy space can damage a brand and customer relationships
- Privacy by design is the FTC's mantra, baking in privacy and security during the development of a product or service

The FTC and OCR

- One overarching theme in digital health privacy is the overlapping jurisdiction of:
 - The Federal Trade Commission, the US privacy regulator with the broadest purview
 - The Dept. of Health and Human Services Office for Civil Rights (OCR), which enforces HIPAA
 - State Attorneys General
- OCR – regulates HIPAA covered entities
 - Healthcare providers that engage in standard electronic transactions
 - Health plans
 - Healthcare clearinghouses
- OCR also regulates business associates

The FTC and OCR

- The FTC's regulatory authority with respect to privacy and security is based upon its authority to regulate "unfair or deceptive acts and practices" under Section 5 of the FTC Act
 - An inaccurate or misleading statement or omission in a privacy policy, user interface or in other consumer-facing material can constitute a deceptive practice
- In 2005, the FTC used the "unfairness doctrine" in an enforcement action involving BJ's Wholesale Club
 - The unfairness doctrine allows the FTC to take action against businesses for failure to have reasonable data-security practices, even in the absence of a deceptive statement on the subject

Consumer-Generated Health Information

- The FTC has taken note of the vast volumes of health information that consumers are sharing through mobile apps, wearable devices, and personal health records, referred to as consumer-generated health information (CHI)
- May 2014: FTC conducts a seminar titled “Consumer Generated and Controlled Health Data”
- April 2016: FTC, in conjunction with OCR and FDA, releases “Mobile Health Apps Interactive Tool”
- October 2016: FTC and OCR put out business guidance titled “Sharing Health Information? Look to HIPAA and the FTC Act”
- December 2017: FTC puts out consumer education titled “DNA Test Kits: Consider the Privacy Implications”
- March 2019: FTC guidance for businesses selling genetic testing kits

OCR's First Mobile Health Privacy Enforcement Action

- April 24, 2017: OCR enters into a no-fault settlement agreement with CardioNet, a wireless cardiac monitoring service provider
 - The first HIPAA settlement involving a mobile health provider
 - \$2.5 million settlement amount
 - Corrective action plan
- Arose out of an incident in which a laptop was lost containing health information of 1,391 individuals
- Resolution agreement alleged that CardioNet had an insufficient security risk analysis and had not fully implemented its HIPAA Security Rule policies and procedures, which were in draft form

FTC Digital Health Privacy Enforcement: Practice Fusion

- June 2016: FTC enters into a settlement agreement with Practice Fusion, an electronic health record company
 - Charged that Practice Fusion misled consumers by soliciting reviews of doctors without disclosing adequately that reviews would be publicly posted, resulting in public disclosure of patients' sensitive personal and medical information

FTC Mobile Health App Tool

- FTC, OCR, and FDA developed a “Mobile Health Apps Interactive Tool”
 - Provides a list of questions that can help an app developer determine whether it is subject to:
 - HIPAA
 - FTC Act
 - FTC’s Health Breach Notification Rule
 - Federal Food, Drug and Cosmetic Act
 - Is your app intended for use in the diagnosis of disease or other conditions?
 - Is your app a “mobile medical device,” such as an accessory to a regulated medical device?
 - Does your app pose “minimal risk” to a user?

Healthcare Mobile Apps

- In February 2016, OCR released “Health App Use Scenarios & HIPAA”
 - Provides examples of how HIPAA applies to mobile apps that collect, store, manage, organize or transmit health information
 - Issued on OCR’s mHealth Developer Portal, which provides guidance and responds to questions from app developers regarding HIPAA
 - Six specific scenarios demonstrating when app developers are, and are not, regulated as HIPAA business associates

Mobile App Scenario 1

- A consumer downloads a health app to her smartphone
- Populates it with her own health information
- No relationship between the mobile app and the consumer's healthcare providers or health plan
- Is the app developer subject to HIPAA regulation?
- Is the app developer subject to FTC regulation?

HIPAA Business Associate Definition

- A business associate is:
 - A person or entity
 - **Acting on behalf of a covered entity**
 - That creates, receives, ***maintains***, or transmits PHI
 - For a function or activity regulated by HIPAA (a covered entity function)
- “Acting on behalf of” language is key to so many digital health privacy issues
- In mobile app Scenario 1, the app developer is “acting on behalf of” the consumer, not a covered entity
- OCR issued a fact sheet clarifying direct liability of business associates:
<https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html>

Mobile App Scenario 2

- Consumer downloads a health app to her smartphone to help manage a chronic condition
- App developer and healthcare provider have entered into an interoperability arrangement at consumer's request to facilitate secure exchange of health information
- Consumer inputs information on the app and directs it to transmit the information to the provider's EHR
- Consumer accesses provider's test results through the app
- Is the app developer a HIPAA business associate?
- What if the app's privacy policy is not posted in the app store where the app is downloaded and is not conspicuously available to the consumer?
- When the consumer is about to send health information from the app to the provider's EHR, should there be some form of "just in time" notification?

Mobile App Scenario 3

- A provider contracts with a health app developer for patient management services
 - Remote patient health counseling
 - Monitoring patients' food and exercise
 - Patient messaging
 - EHR integration
- Provider instructs her patients to download the app to their smartphones
- Is the developer a business associate?
- Does the FTC still have jurisdiction to regulate the developer?

OCR or FTC Regulation? Follow the Money

- Based upon a series of OCR guidance documents, it seems that one test for determining whether an app developer or other digital health company is acting on behalf of the consumer or the covered entity is:
 - Who's paying for the service?
 - If the consumer is your customer, you will probably be subject to FTC regulation, but not HIPAA
 - If the provider is your customer, you will probably be a HIPAA business associate
- In the prior scenario, if the developer also offered a direct-to-consumer version of the same app, that would not be subject to HIPAA

Questions to Ask Regarding Business Associate Status

- OCR's Health App Guidance provides a series of questions that developers should ask to determine if they are business associates:
 - Does the app create, receive, maintain, or transmit identifiable health information?
 - Is the health app selected independently by the consumer?
 - Are all decisions to transmit health data to third parties controlled by the consumer?
 - Does the developer have any contractual or other relationships with third-party entities besides interoperability agreements?

Close Questions/Gray Areas

- But what if the provider is paying for only a portion of the costs associated with the app?
 - Paying 75% of a subscription fee for the app?
 - And offering members only one choice of app?
 - Providing a smartphone or tablet to be used to download the app?

The Consequences of BA Status

- Whether or not a developer is a business associate may have a significant impact on the developer's information collection and disclosure practices
 - If a BA, then BA is acting on behalf of the healthcare provider or health plan and is governed by rigorous HIPAA privacy rules
 - With limited exceptions, the developer can use and disclose PHI only to provide the contracted services to the covered entity
 - If not a BA, then developer will be covered by the FTC's Section 5 enforcement authority
 - Developer has latitude to use and disclose personal information collected through the app so long as it is not misleading consumers or causing substantial injury to consumers in ways that are more harmful than helpful to consumers or the marketplace overall

Bifurcated BA Status?

- For an app developer that has both HIPAA business associate and consumer-directed operations, it may be necessary to segregate personal information collected through the two channels
 - Different privacy rules apply
 - Also different security rules
 - Although the HIPAA Security Rule is generally viewed as representing a reasonable, flexible data security standard
- Although HIPAA's "hybrid entity" concept applies only to covered entities, is it reasonable to assume that a similar approach could be applied to business associate entities with BA and non-BA functions?

Encouraging Portability

- OCR and the Office of the National Coordinator for Health Information Technology (ONC) are seeking to promote portability of health information
 - The 21st Century Cures Act directs HHS to:
 - Address information blocking
 - Promote trusted exchange of health information
 - The Cures Act calls for the development of APIs that enable users to access and use health information “without special effort”
- Final CMS and ONC rules were released on March 9, 2020, published in Federal Register on May 1
- In light of COVID-19, the agencies extended compliance deadlines by 3-6 months
- For example, new Condition of Certification for information blocking will not be enforced until February 1, 2021

OCR, HIPAA and COVID-19

- While COVID-19 is a unique public health crisis, other emergency situations also test the limits of the HIPAA Privacy Rule.
- HIPAA is not intended to be an obstacle to a healthcare organization's essential treatment, emergency response, and public health functions.
- OCR has issued several bulletins, announcements and guidance documents.
- March 17, 2020: OCR announces, effective immediately, that it will exercise its enforcement discretion and waive potential HIPAA violations against healthcare providers that serve patients through "everyday communications technologies" during the COVID-19 nationwide public health emergency.
 - Applies to widely available communication apps like FaceTime and Skype
 - When used in good faith
 - For any telehealth treatment or diagnostic purpose
 - Regardless of whether the treatment service is directly related to COVID-19
 - Does not apply to "public-facing communication apps" such as Facebook Live, Twitch, and TikTok

OCR, HIPAA and COVID-19

- April 2, 2020: OCR announces, effective immediately, that it will exercise its enforcement discretion and will not impose penalties for violations of certain provisions of the HIPAA Privacy Rule against healthcare providers or their BAs for the good faith uses and disclosures of PHI by BAs for public health and health oversight activities during the COVID-19 public health emergency.
 - Applies even if the BAA doesn't provide for this use/disclosure, and only if:
 - 1. the BA makes a good faith uses and disclosures of PHI by BAs for public health and health oversight activities; and
 - 2. the BA informs the CE within 10 calendar days after the use or disclosure occurs (or commences, with respect to uses/disclosures that will repeat over time)
 - Examples include uses/disclosures for or to:
 - the CDC, or similar state public health authority, for the purpose of preventing or controlling the spread of COVID-19; or
 - CMS, or similar state health oversight agency, for purpose of overseeing and providing assistance for the healthcare system as it relates to the COVID-19 response

Business Associates and Contact Tracing

- An activity tracker app offered by a health plan to its members may collect geolocation data that is useful in COVID-19 contact tracing
 - Can this business associate share geolocation data with a state public health authority?
 - Yes, because the disclosure would be permitted for the health plan under HIPAA
- The app developer must notify the health plan within 10 days
 - The developer works with many covered entities so notification could be challenging
 - OCR is flexible regarding form of notification, can be an email
 - But BA needs to maintain documentation of the notice

The California Consumer Privacy Act

- CCPA contains an exception for HIPAA covered entities and business associates, and clinical trials data
- For digital health businesses that do not qualify for its HIPAA exception, the CCPA imposes new requirements
 - Right to notice
 - Right to access
 - Right to delete
 - Right to opt-out of sale of personal information
 - Right to equal service and price
- Business groups have lobbied for extension of July 1, 2020 enforcement date in light of COVID-19, but the California Attorney General's office has not indicated any willingness to extend

Activity Trackers and Wearable Devices

- Proliferation of activity trackers and other sensor-based wearables raises many of the same privacy regulatory issues as health mobile apps
- Activity trackers are often sold directly to the consumer
 - In those cases, the company would not be a HIPAA business associate because it is acting on behalf of the consumer, not on behalf of a covered entity
- But if a health plan enters into an arrangement to purchase activity trackers for its members, that may trigger a BA relationship
 - Still a facts and circumstances test: How much is the health plan paying? How much control does the plan member have over the choice of the device and sharing information with the plan?

Employer vs. Employer Group Health Plan

- If an activity tracker is sold to an employer (in its capacity as an employer) to make the devices available to its workforce
 - Probably NOT a business associate relationship
 - An employer, acting in its capacity as an employer, is not a HIPAA covered entity and the medical information they hold is not PHI
- HOWEVER, if the activity trackers are sold to the employer's group health plan (which is separate and legally distinct from the employer/plan sponsor)
 - Then the activity tracker company probably would be a business associate
 - Employer group health plans are almost always health plan covered entities under HIPAA

Wellness Programs

- Healthcare mobile apps are being offered as part of some workplace wellness programs
- Are such apps regulated by OCR or the FTC?
 - If the wellness program app is offered through the employer's group health plan?
 - If the wellness program app is offered directly by the employer?
- See "HIPAA Privacy and Security and Workplace Wellness Program" at [HHS.gov](https://www.hhs.gov)

Scenario: Smart Glucose Meter

- Manufacturer of a smart glucose meter that stores consumer's glucose level information in the cloud
- If a manufacturer sells the meter directly to the consumer, how is the manufacturer regulated?
- Presentation of privacy policy
 - What if the manufacturer includes its privacy policy only on its corporate website?
 - What if the consumer clicks acceptance of a privacy policy when she accesses data in the cloud?
- If a manufacturer sells smart glucose meters to a medical practice, which then offers them to patients, how is the manufacturer regulated?
 - See OCR cloud computing guidance

Scenario: Health Plan PHR

- A health plan offers a PHR for its plan members so that they can better manage their health
 - Uses the PHI to facilitate granting HIPAA rights to access and amend PHI, obtain an accounting of PHI disclosures, and receive a Notice of Privacy Practices
 - How will the health plan's PHR be regulated?

Scenario: Direct-to-Consumer PHR

- PHR company offers a similar PHR directly to consumers
- Plan member can exercise right to access health plan's PHI and place that copy in their PHR
- PHR requires users to agree to its privacy policy at account creation
- PHR company claims in its advertising to be "HIPAA compliant"
- PHR company claims to have voluntarily implemented HIPAA Security Rule standards

Virtual Assistants and Healthcare

- Do voice-activated virtual assistants like Amazon's Alexa and Google Assistant represent the next wave of digital health innovation?
- Health systems are beginning to experiment with virtual assistants to keep patients informed and engaged
- Alexa currently offers:
 - Medical information
 - "Medical advice" from a "physician A.I."
 - Tool that lets diabetes patients track their blood sugar information by telling it to Alexa
- Potential HIPAA and FTC Act Section 5 issues?
 - Verification of identity issues
 - "Verbal" disclosures

AI and Healthcare

- Artificial intelligence (AI) offers potential for improving healthcare but also potential privacy challenges
- Development of AI algorithms requires access to vast amounts of health information – which raises privacy concerns
- Are HIPAA business associates permitted to use PHI to develop AI algorithms?
- Does the sophistication of AI make it less feasible to de-identify PHI?
- Under Section 5 of the FTC Act, how transparent do companies need to be about use of personal information for development of AI algorithms?

AI and HIPAA

- Is it possible for the AI developer to use de-identified data?
 - Use of the “safe harbor” or “expert determination” method
- Is AI processing a “use” of PHI under HIPAA?
- In December 2000 commentary to the HIPAA Privacy Rule, HHS stated:
 - “We interpret ‘use’ to mean only the uses of the product of computer processing, not the internal computer processing that generates the product.”
 - This statement could be interpreted to mean that when an algorithm “learns” by processing health information in a database, that is not a “use” of PHI subject to HIPAA restrictions
 - However, technology (and OCR’s view of it) has changed a lot since 2000, and this non-binding guidance may no longer hold

The Internet of Things

- In 2013, the number of mobile devices connected to the internet became greater than the number of people in the world
- The number of devices connected to the internet worldwide is estimated to reach more than 20 billion by 2020
- Many of these devices, such as activity trackers and smart medical devices, collect CHI
- How do you implement reasonable privacy and security for this enormous proliferation of connected devices?
- Malware such as Mirai and Ares (August 2019) target security vulnerabilities in IoT devices to create botnets

FTC Polices IoT

- The FTC's enforcement powers extend to cover privacy and security risks posed by the IoT
 - FTC Commissioner Slaughter gave a 2018 speech "Bringing Security and Transparency to the Internet of Things"
 - No specific privacy law that directly targets IoT data collection and security
 - FTC regulates IoT based on jurisdiction over unfair and deceptive trade practices under Section 5 of the FTC Act
- Section 5 doesn't specifically address application of privacy principles to cutting-edge technologies
 - Concepts of deception and unfairness may be interpreted to cause companies to examine (1) what they are telling consumers about data collection and use, (2) what consumers understand about those practices, (3) what are their data security practices

FTC IoT Enforcement: D-Link

- July 2019: FTC enters into settlement agreement with D-Link Systems, Inc., a smart home products manufacturer
- Company was charged with misrepresenting that its wireless routers and internet connected security cameras had reasonable security
- 2017 complaint alleged that vulnerabilities in D-Link's routers and cameras caused consumer information, including live video and audio feeds, to be exposed to third parties and vulnerable to hackers

Adapting Privacy Best Practices to Connected Devices

- Privacy regulation is based on traditional notions of “notice” and “consent”
 - But those concepts must be adapted to apply to IoT
- Wearable fitness trackers typically don’t have a user interface to serve as a means to present consumers with choices about data collection
- Connected devices may become too numerous for consumers to effectively manage their information
- Companies urged to “get creative” about providing privacy transparency and control for consumers to manage their data
 - Example: “Command center” that runs multiple household devices and can describe in simple terms how information is being collected and used across those devices

The FTC Weighs In

- In January 2015, the FTC issued the report “Internet of Things: Privacy & Security in a Connected World”
 - Based on input from technologists, academics, industry representatives, consumer advocates at November 2013 FTC workshop in DC
 - Report is limited to IoT devices that are sold to or used by consumers
 - Recommended practices document, does not have the force of law or regulations
 - But may provide insight into future FTC enforcement actions

Personal Health Records

- What is a Personal Health Record (PHR)?
- No universal definition
- Generally, an electronic record of an individual's health information by which the individual controls access to the information and may have the ability to manage, track, and participate in his or her own care
- Mobile health apps and some IoT devices can take on characteristics of a PHR depending upon amount and type of CHI collected
- Distinct from an electronic medical record (EMR), which is maintained and largely controlled by a healthcare provider

HIPAA and PHRs

- OCR issued guidance document “Personal Health Records and the HIPAA Privacy Rule”
- Earlier statement of many of the principles elaborated upon in mobile health app and cloud computing guidance
- Consumer-directed PHRs not offered by HIPAA covered entities are not subject to HIPAA regulation
- The fact that a consumer places copies of their medical records in a PHR does not create a business associate relationship
- PHR vendor must be “acting on behalf of” a HIPAA covered entity to be a business associate

FTC's Health Breach Notification Rule

- Pursuant to HITECH, the FTC issued a Health Breach Notification Rule in 2009
 - Generally mirrors the HIPAA Breach Notification Rule
- Applies to:
 - A vendor of PHRs
 - A PHR-related entity
 - A third-party service provider for a vendor of PHRs or a PHR-related entity
- Vendors and PHR-related entities must notify affected persons, the FTC and, in some cases, the media if there's a breach of unsecured, individually identifiable health information
 - Third-party service providers must provide upstream notification

Vendor of Personal Health Records Defined

- A business is a vendor of personal health records if it “offers or maintains a personal health record”
- A PHR is defined as an electronic record of “identifiable health information on an individual that can be drawn from multiple sources and is managed, shared, and controlled by or primarily for the individual”

Session Takeaways

1. Navigating this new digital health privacy landscape requires:
 - a. Keeping an eye on the latest enforcement actions by OCR, FTC, and state Attorneys General
 - b. Reviewing the latest guidance documents interpreting laws and regulations like HIPAA and Section 5 of the FTC Act
 - c. Incorporating emerging privacy and security best practices, including Privacy by Design and Security by Design
2. Remember that many digital health companies straddle multiple privacy and security regulatory regimes
3. KNOW WHEN YOU'RE CROSSING ONE OF THOSE LINES!



Biography



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W. Reece Hirsch co-heads the firm's privacy and cybersecurity practice and counsels clients on a wide range of US privacy issues, specializing in healthcare privacy and digital health. Reece counsels clients on development of privacy policies, procedures and compliance programs, security incident planning and response, and online, mobile app, and Internet of Things privacy. In a Chambers USA ranking, Reece was recognized by his peers as "a consummate expert in privacy matters."

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Lauren Z Groebe focuses her practice on regulatory and transactional matters affecting clients in the healthcare sector. She counsels hospitals, health systems, hospices, pharmacies, and private equity clients, among others, across a range of regulatory issues, including matters related to compliance with HIPAA, state privacy and security laws, CCPA, the 340B Program, the Sunshine Act, fraud and abuse laws, Medicare and Medicaid enrollment, and state licensure requirements. Lauren also advises clients on the corporate and healthcare regulatory aspects of merger and acquisition transactions with a specific focus on privacy and security compliance.

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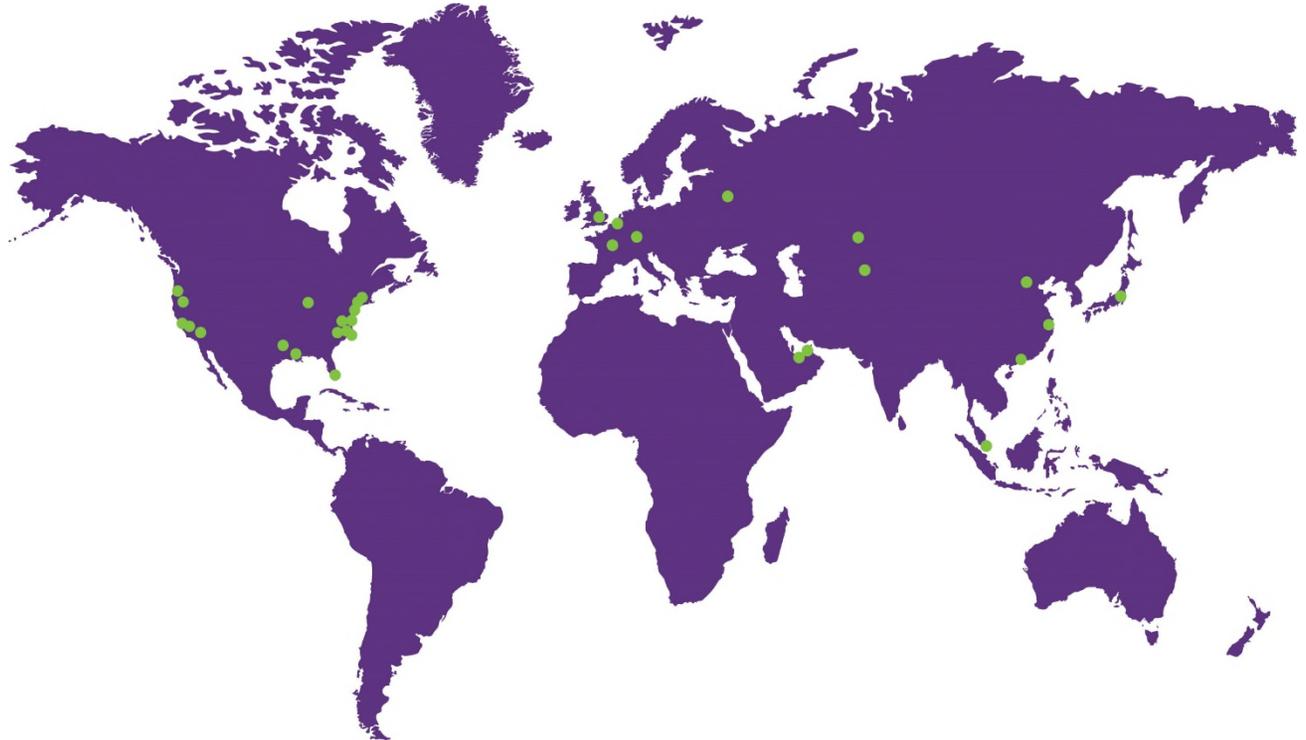
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