FDASIA TAXONOMY SUBGROUP SUMMARY REPORT

Membership: The FDASIA Taxonomy subgroup was comprised of members of the larger the FDASIA workgroup, and had representation from the commercial software development, patient advocacy, research and development, regulatory, academic and conventional medical device manufacturing, developer and end-user domains.[1] The subgroup was co-chaired by Patricia Flatley Brennan and Meghan Dierks. This report represents the output of the subgroup's discussion and deliberation over the past several months.

Process: The subgroup met via teleconference four times, interfaced during the on-site FDASIA workgroup meeting held in Washington DC on 30 May 2013, and carried out additional significant collaborative work via online/email and written correspondence. Members of the subgroup also participated in, and contributed or reported out on each of the larger FDASIA workgroup teleconferences.

Interpretation of Charge: The Taxonomy subgroup interpreted its charge as provided at the outset by the participating Federal Agencies to be the following:

> Develop a strategy for establishing what forms of Health IT would be *potentially subject to, or eligible for evaluation under* a new, appropriate, risk-based regulatory framework that promotes innovation, protects patient safety, and avoids unnecessary and duplicative regulation.

The subgroup explicitly stated that *in-scope* was intended to mean that a particular form or class of Health IT is *potentially subject to, or eligible for evaluation under* a new, appropriate, risk-based regulatory framework. The Taxonomy subgroup was explicit in stating that in-scope is not intended to mean 'subject to, or requiring a regulatory control.' Because the new risk-based regulatory framework might include regulatory exclusion criteria (e.g. a product meets specific defined criteria that excludes it from further regulatory control), the subgroup acknowledged that some forms of Health IT deemed to be in-scope for the new risk-based framework might ultimately not be subject to any specific controls. Based on this interpretation of charge, the Taxonomy subgroup generated a work product that was intended to enable the Regulatory and Risk & Innovation subgroups, respectively, to establish bounds on deliberation and define the intended target of final recommendations to the larger HIT Policy Committee. This document provides an overview of the generalized model to characterize Health IT and a guide to the decision process that designates whether a specific Health IT product is *potentially subject to, or eligible for evaluation* the risk based regulatory framework. The appendix following this two-page summary documents the guiding principles, process followed and the work products generated by the Taxonomy subgroup.

Characterizing and Describing Health IT: The subgroup identified eight characteristics of Health IT that were thought to be important in describing the forms of Health IT (see Table 1).[2] The intent was to characterize Health IT along a number of dimensions that attend not only to the physical nature of the product, system or application, but also to its developmental life cycle,

[1] See appendix for full sub-group membership

[2] The Taxonomy subgroup reviewed sevaral existing statutory definitionsof health information, health IT and medical device as a frame of reference: Definition of Health Information - SSA § 1171(4); 42 U.S.C. 1320d; Definition of Health Information Technology - HITECH Act 2009 amendments to [SSA § 42 USC § 300jj]; Definition Medical Device [Federal Food, Drug and Cosmetic Act 21 CFR 800-1299]

or its intended use and users. These eight characteristics are intended to form the core of an evaluation template or process. We deliberately did not specify the terminology that should be used to instantiate each characteristic. We acknowledged that no single characteristic directs whether or not a single Health IT is *potentially subject to, or eligible for evaluation* under the proposed new risk-based regulatory framework.

Determining whether or not a specific Health IT product should be subject to risk based regulation: Health IT products typically are designed and engineered to deliver or support a specific clinical function. Members of the subgroup concluded that the **function** (i.e., use in clinical care) of Health IT drives much of the clinical benefit or effectiveness. For this reason, the subgroup concluded that the the determination of whether a specific Health IT product was *potentially subject to, or eligible for evaluation under* a new, appropriate, risk-based regulatory framework be based on **functionality.** The subgroup developed and proposed use of a decision tree structure that would serve as an aid in assigning a form or type of Health IT to one of two states:

Table 1: Eight Key Dimensions of HIT

1. Intended use
2. Conditions of use
3. User type
4. Developer/ 'Manufacturer' Type
5. Distribution model for the software, data transmission mode (e.g., 'Wireless' vs. wired, mobile vs.fixed, installed versus 'Software as a Service' (SaaS)
6. Phases of product lifecycle, including:
   - implementation
   - configuration and user modification of base 'code' or base product
   - maintenance
   - sunsetting
7. Product categories
8. Other

a) Subject to, or eligible for evaluation under a new, risk-based regulatory framework proposed by the FDASIA workgroup (and endorsed by the HIT Policy Committee); or
b) Likely not subject to the new, risk-based regulatory framework

The decision tree is depicted in the appendix in Figure 2. Each node reflects a decision point that the subgroup believes important.

Application of the taxonomy and decision tree: We envision that the taxonomy and decision tree are used in combination to assign Health IT for consideration under the new, risk-based regulatory framework in the following manner: A Health IT product would be described by the 8 characteristics from Table 1, assessed in terms of its designed functionality, and then be subjected to the decision tree. If the decision tree process yields a determination that the Health IT product is in-scope for the new proposed risk-based regulatory framework, it would enter into a larger process of assessment as proposed by the FDASIA Risk Framework subgroup.

Appendix

Organizing Principles: The subgroup developed and used several guiding principles to inform its work.

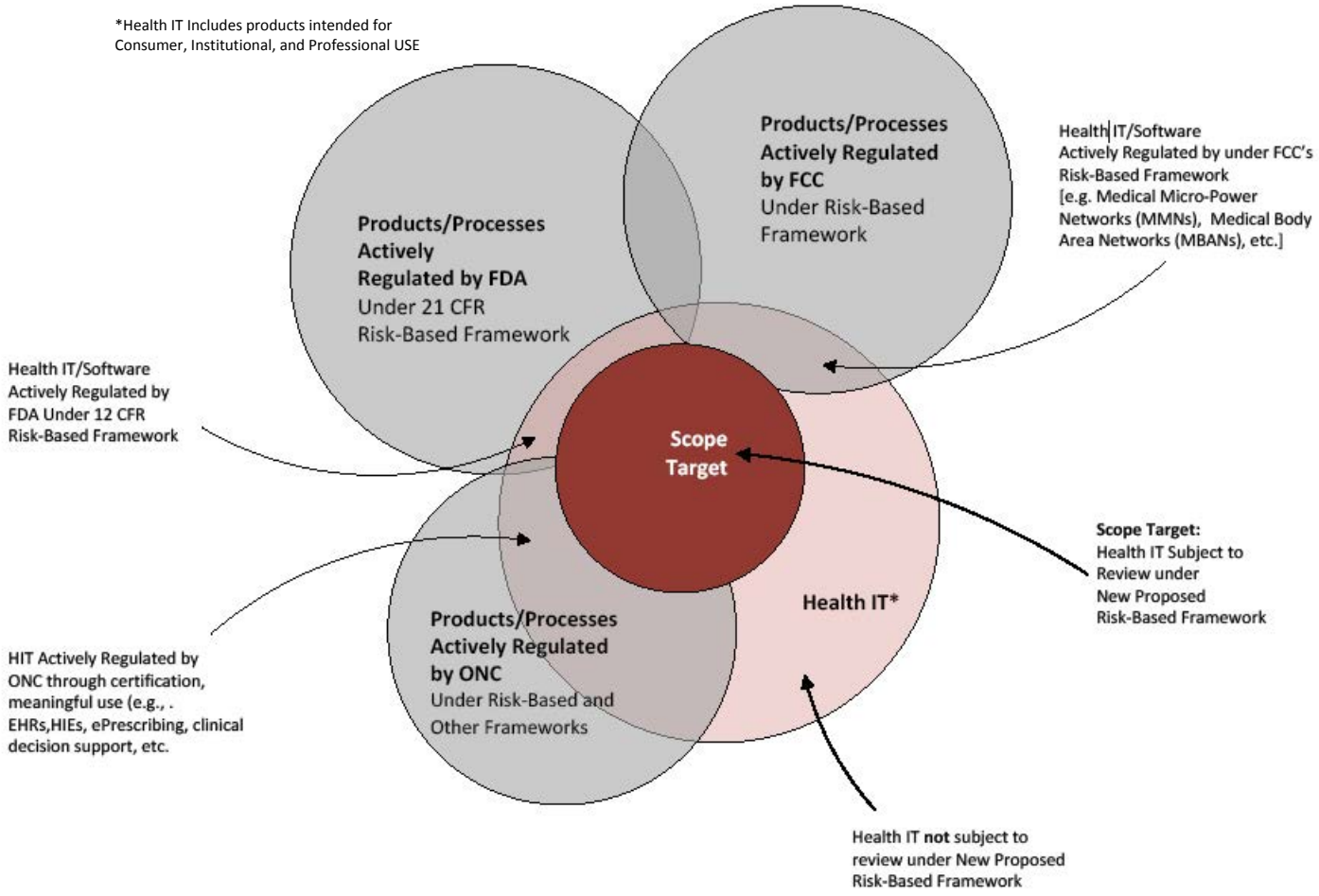
1. Develop a robust and flexible taxonomy of Health IT that is that is relevant to the task of assessing risk, but that is not anchored in existing products or present-day manifestations of Health IT. This strategy was intended to avoid ambiguity/uncertainty when a future technology does not readily map to a currently definable 'HIT category'.
2. Establish clinical functionality as the criterion for basing the determination of whether or not a particular technology might be subject to the proposed new risk-based regulatory framework.
3. Adopt a decision tree approach to help elucidate the functionality of a specific form of Health IT. Functionality will help distinguish between two similar innovations, one requiring risk-based regulation and one not.
4. Avoid creating a prescriptive or inclusive inventory of current Health IT for determining what should be regulated
5. If, by virtue of its functionality, a 'part' of a Health IT product met the criteria for in-scope, then the 'whole' product should be considered in-scope. For example, if an algorithm embedded in a larger software application is considered in-scope, the entire software application would be considered in-scope.

Products Actively Regulated under FDA's Medical Device Regulation (21 CFR): Members of the subgroup acknowledged FDA's existing risk-based regulatory framework for medical devices and drew several important conclusions. First, the subgroup agreed that many existing and foreseeable forms of Health IT meet the statutory definition of a medical device and therefore theoretically would be subject to FDA's risk-based regulatory framework for medical devices. The subgroup also acknowledged that the FDASIA workgroup was formed in part to address concerns about the appropriateness or applicability of the conventional medical device regulatory framework to many forms of Health IT. Finally, the subgroup recognized that there are some categories of Health IT products that have been legally manufactured and marketed for some time in the US, and are actively regulated by the FDA under 21 CFR. Examples of these products include, but certainly are not limited to:

- Computer-aided detection algorithms used on medical imaging data sets,
- Software algorithms that automatically mark or identify electroencephalograph waveforms for spikes in order to aid in identification of electrographic seizures, or seizure-like events
- Blood bank laboratory information systems
- Decision support systems intended for use in prediction of hourly fluid volume requirements for resuscitation of the critically ill patient
- Picture Archiving and Communication Systems

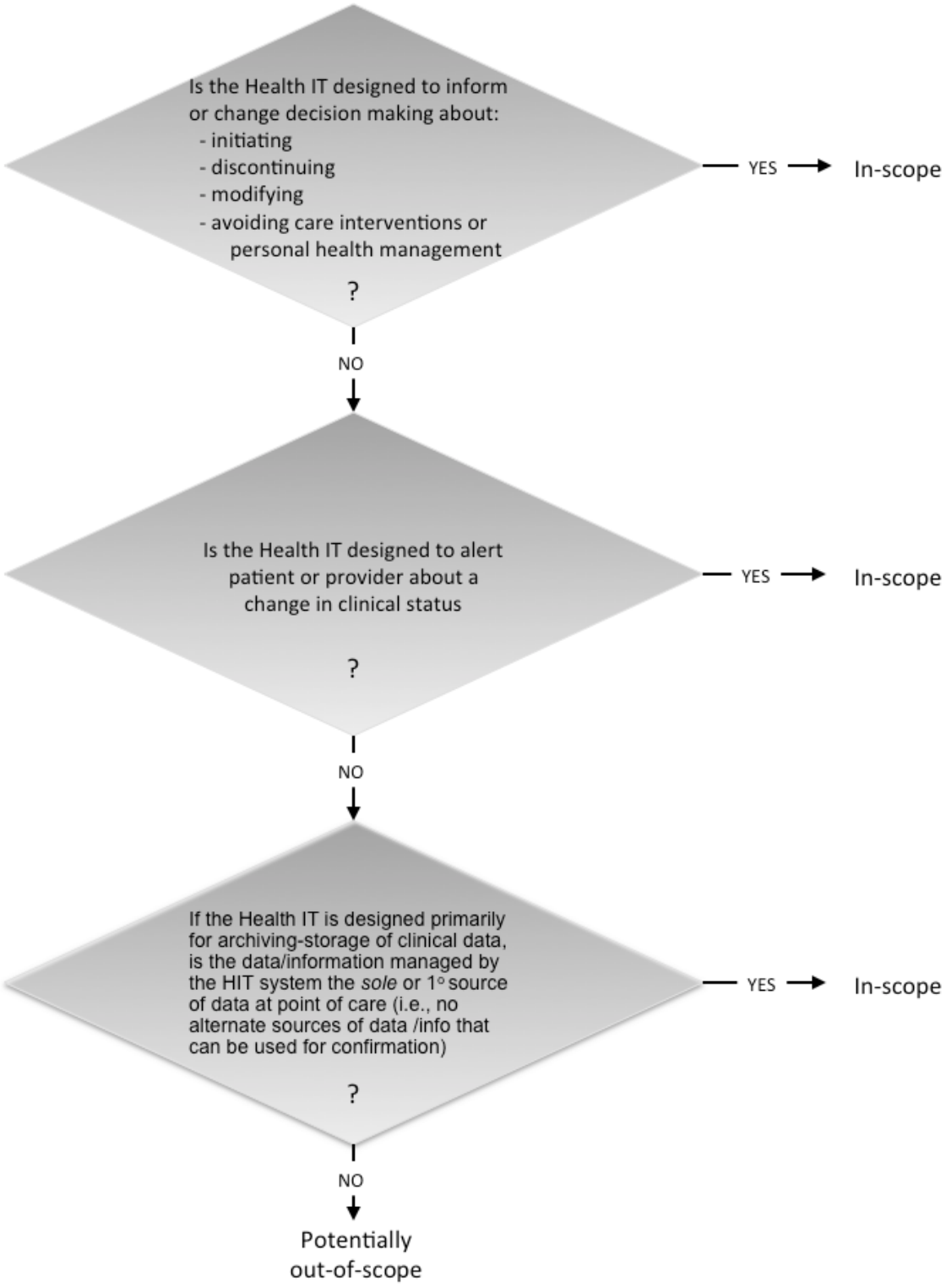
The subgroup recognized that some products that at this time are actively regulated by the FDA as medical devices, which include some Health IT. Figure 1 summarized the state of Health IT and FDA regulation that the subgroup subsequently considered.

Figure 1: Health IT Taxonomy



Interpretation: The large pink circle encompasses new and existing Health IT. Figure 1 represents the relationship of the "scope target" discussed by the taxonomy group with products currently regulated or certified by the FDA, FCC, and ONC. The gray circles encompass the set of products that are currently regulated or certified by the FDA, FCC, and ONC. The dark red circle encompasses new or existing Health IT products to which the risk-based regulatory framework sought by FDASIA could be applied. The intersection of the gray circles with the dark red circle represents Health IT currently regulated by the three agencies.

Figure 2: Scoping Decision Tree, emphasizing product functionality.



In-scope/Out-of-scope Health IT Exemplars: After deliberation and application of the decision tree process, the Taxonomy subgroup generated a list of exemplar Health IT products that, in addition to products that are actively regulated by the FDA under 21 CFR, we considered out-of-scope for the new regulatory framework. We also generated a list of exemplar HIT products that were considered in-scope. For illustrative purposes, these are presented in Table 2.

Table 2: Health IT Exemplars

Potentially Subject to New Risk-Based Regulatory Framework	Not Likely Subject to New Risk-Based Regulatory Framework
• EHRs (installed and SaaS) • Hospital information systems-of-systems • Decision support algorithms • Visualization tools for anatomic, tissue images, medical imaging and waveforms • Health information exchange software • Electronic/robotic patient care assistants • Templating software tools for digital image surgical planning	• Claims processing software • Health benefit eligibility software • Practice management / Scheduling / Inventory management software • General purpose communication applications (e.g., email, paging) used by health professionals • Software using historical claims data to predict future utilization/cost of care • Cost effectiveness analytic software • Electronic guideline distribution software • Disease registries

Taxonomy Sub-group Membership:

Patricia Flatley Brennan (Co-Chair), University of Wisconsin-Madison
Meghan Dierks (Co-Chair), Harvard Medical Faculty, Division of Clinical Informatics
Todd Cooper, Breakthrough Solutions Foundry, Inc.
Richard Eaton, Medical Imaging & Technology Alliance
Elisabeth George, Philips Healthcare
T. Drew Hickerson, Happtique, Inc.
Mary Anne Leach, Children's Hospital Colorado
Meg Marshall, Cerner Corporation
Mary Mastenbrook, Consumer
Anna McCollister-Slipp, Galileo Analytics
Jackie McCarthy, CTIA - The Wireless Association
Michael Swiernik, MobileHealthRx, Inc.