AdvaMedDx DRAFT Comparative Summary:

DAIA Discussion Draft (3-17-2017) – FDA TA (8-3-2018) – VALID (12-6-2018)

	DAIA	FDA TA	VALID
IVCT definitional scope and exemptions	Excludes 1) any test that is a biological product intended to screen blood, tissues, or organs for infectious diseases, or determine the compatibility of a donor; 2) any test intended by its developer solely for nonclinical use or public health surveillance.	The term IVCT means a test intended to be used in the collection, preparation, analysis, or in vitro clinical examination of specimens taken or derived from the human body for the purpose of identifying, diagnosing, screening, measuring, detecting, predicting, prognosing, analyzing, or monitoring a disease or condition, including a determination of the state of health, OR selecting, monitoring or informing therapy or treatment for a disease or condition. The definition of IVCT includes a test protocol, a test platform, an article for taking or deriving specimens from the human body for such purposes, and a component, part, *or accessory* of a test, whether alone or in combination, including but not limited to reagents, calibrators, and controls. However, IVCTs that are components, parts, or accessories are exempt from the requirements established in the legislation if they are intended solely for use in the development of another IVCT and, if they are offered for clinical use after the date of enactment, they are labeled accordingly. Blood, blood components, and human cells or tissues are not included in the definition of IVCT until such article is offered for clinical use	Generally tracks with FDA TA, except "accessories" are not included in the definition of IVCT.

		as a component, part, or accessory of an IVCT by the establishment that collected such article. Articles used for invasive sampling, general purpose laboratory equipment, and articles used solely for personal protection during testing procedures are not considered IVCTs. While not excluded from the definition of IVCT, subject to certain exceptions, manual tests, public health surveillance tests, law enforcement tests, and investigational use tests would be exempt from the requirements established by the legislation. So long as the developer maintains documentation that the applicable criteria continue to be met, tests for rare diseases (fewer than 8,000 individuals per year in the U.S. would be subject to such IVCT) would be exempt from premarket review (along with low-risk IVCTs and precertified IVCTs). Custom (single patient) and low-volume (< 5 patients) tests would be exempt from pre-market review, QS requirements, and notification requirements. Grandfathered tests are exempt from premarket review, QS requirements, and labeling. Tests that were exempt from 510(k) prior to the effective date are exempt from premarket review as are tests that were not offered prior to the effective date but fall within such category of tests.	
Regulatory	FDA would have the authority to	Establishes in the FFDCA a regulatory	Same as FDA TA

framework	review the design, development, validation, production, manufacture, preparation, propagation, assembly, and modification of an IVCT.	framework for the review and oversight of in vitro clinical tests, separate and distinct from the medical device framework.	
New Center	Establishes a new Center at FDA for IVCTs.	No new center established.	Same as FDA TA
Jurisdiction	Establishes three distinct categories of activity and jurisdiction (FDA – test development and manufacturing; CMS/CLIA – laboratory operation; States – medical use and interpretation).	Does not change or modify CLIA. Requires FDA, to the greatest extent possible, unless necessary to protect public health, avoid undertaking programmatic regulatory functions separately being undertaken pursuant to CLIA.	Same as FDA TA
Registration and Notification	Before the earlier of offering an IVCT or submitting an application, a developer must register with FDA. Grandfathered test developers must register within 180 days of enactment. Developers must notify FDA of a change in their registration within 30 days of making such change and submit an updated registration annually. Developers must list with FDA information on each IVCT offered. Different timeframes apply for grandfathered tests. FDA must establish and maintain a list of all IVCTs approved or otherwise required to be listed.	IVCT developers shall annually register with FDA and be subject to inspection. Each developer shall submit or update a notification to FDA annually containing detailed descriptions (i.e., notification elements) of each IVCT they offer. Different timeframes will be established (though are not included in the language) based on whether the IVCT was listed as a device or if it is a grandfathered test. Notification information will be posted on FDA's website subject to certain limitations. A "test group" means one or more IVCTs that all have the following notification elements in common: (A) Substance or substances measured by the IVCY, such as analyte, protein, or pathogen; (B) Type or types of specimen or sample; (C) Test method; (D) Test purpose, such as screening, predicting, or monitoring;	Same as FDA though the "disease or condition" and "intended patient population" notification elements used to establish a test group are made plural: "diseases or conditions" and "intended patient populations".

		(E) Disease or condition for which the IVCT is intended for use; (F) Intended patient population; and (G) Context of use The establishment of a test group is key for purposes of determining risk classification, whether a test is first-of-a-kind, determining whether a modification is required to be a submitted for review, establishing mitigating measures, and other components of the framework.	
Risk Based Classification	Each test would be classified as high-risk, moderate-risk, or low-risk with the ability for risk-reducing factors and mitigating measures (e.g., technology and clinical use are well characterized, confirmatory or adjunctive tests are available, etc.) to impact classification or reclassification decisions and applicable regulatory requirements. For example, an IVCT shall be regulated as high-risk if a clinically significant inaccurate result for the intended use would cause serious or irreversible harm, prolonged disability, or death, to the patient or public base on a failure to treat, an incorrect treatment, or an invasive procedure, if such inaccurate result were undetected when used as intended, unless there is one or more risk reducing factors that has the capacity to prevent or detect such inaccurate result or otherwise mitigate the risk of such inaccurate result. If FDA fails to issue certain classification determinations within required timeframes, recommended	A high-risk IVCT means a test or category of tests where an undetected inaccurate result from such test or category of tests, when used as intended, would likely cause serious or irreversible harm or death to a patient, or would otherwise cause serious harm to the public health AND the likelihood of adverse patient or public health impact is not remote. An IVCT is not considered high-risk if mitigating measures are established and applied to sufficiently mitigate the risk of inaccurate results taking into account the degree to which the technology for the intended use of the IVCT is well characterized, and the criteria for performance are well established to be sufficient for the intended use; AND the clinical circumstances (including clinical presentation) under which the IVCT is used, and availability of other tests (such as confirmatory or adjunctive tests) or relevant material standards. Moderate-risk IVCTs are not part of the proposed construct. A low-risk IVCT means a test or category of	Same as FDA TA, though low-risk definition appears to be incorrectly restructured (i.e., drafting error).

	classifications (by the developer or an advisory panel) will be considered final. Platforms are classified and regulated separately from the IVCT with which it is used and are to be classified as low-risk. An IVCT intended to be performed on the platform shall be classified according to its intended use and independent of the platform.	tests where an undetected inaccurate result from such test or category of tests, when used as intended, would cause minimal or no harm or disability, or immediately reversible harm, or would lead to only a remote risk of adverse patient or public health impact; OR could cause non-life threatening injury or injury that is medically reversible, or delay unnecessary treatment and mitigating measures are sufficient to prevent, detect or otherwise sufficiently mitigate the risk associated with such inaccurate result. There are is not a specific process with mandated timelines for FDA review and issuance of decisions related to classification or reclassification. Based on new information, including the establishment of mitigating measures, FDA may, upon his own initiative or upon petition of an interested person, change the risk designation of a test group after publication of a notice in the FR and an opportunity for public comment following a proposed notice. FDA will maintain a list on its website of IVCTs or categories of IVCTs that have been designated as low-risk and may add to the list on its own or in response to a request by any person. This list shall include tests that were offered for clinical use prior to the effective date and were exempt from submission of a report under 510(k) (including class II 510(k) exempt devices and excluding class I reserved devices) OR tests that were not offered for clinical use prior to the effective date, are not test platforms, and falls within a category of tests that were exempt from submission of a	

		report under 510(k) prior to the effective date (including class II 510(k) exempt devices and excluding class I reserved devices).	
Review Standards and Mitigating Measures	Establishes "reasonable assurance of analytical validity and clinical validity" as the IVCT standard for review and defines those terms. The term 'mitigating measures' means, measures that the Secretary determines, based on available evidence, are necessary to provide a reasonable assurance of the analytical validity and clinical validity, or probable clinical validity, as applicable, of an in vitro clinical test for its intended use, in a particular risk classification.	The "relevant standard" depends on the regulatory pathway followed by the IVCT to be legally marketed. Typically, the relevant standard is a reasonable assurance of analytical and clinical validity. For provisional approvals, the relevant standard is reasonable assurance of analytical validity and probable clinical validity. With respect to articles for taking or deriving specimens from the human body, the relevant standard means a reasonable assurance of analytical validity and, where applicable, safety. Mitigating measures are requirements FDA determines are necessary for an IVCT or category of IVCTs to continually comply with (and document) in order to meet the relevant standard for its intended use or to mitigate the risk of harm ensuing from a false result or misinterpretation of any result. Such measures can involve labeling, advertising, website posting of information, testing, clinical studies, postmarket surveillance, user comprehension studies, training, conformance to standards, and performance criteria. FDA may establish, change, or withdraw mitigating measures for any test group or test groups by administrative order published in the FR following publication of a proposed mitigating measure order and consideration of comments to a public docket. Any special controls or restrictions applicable to an IVCT or test group based on prior regulation as a medical device shall be deemed mitigating measures upon the	Tracks FDA TA with several changes: The term "adequately" appears in the definitions of analytical and clinical validity in the TA and is instead pulled into the review standard in VALID. There is no provisional approval pathway. Mitigating measures provisions explicitly apply to precertification.

		effective date.	
Premarket review – application contents	Establishes premarket requirements, which differ based on risk-classification, to meet the approval standard. Exempts certain categories of tests, including low-risk IVCTs and tests for rare diseases (includes test intended for a disease with an incidence of 8,000 or fewer per year or a prevalence of 50,000 or fewer in the U.S.), from premarket review altogether, requiring only FDA notification of name and intended use within ten days after first offering. For *high-risk tests*, prior to offering, the developer must submit evidence that demonstrates reasonable assurance of analytical and clinical validity for its intended use. Among other components, an application must include a summary of relevant valid scientific evidence and the protocol and summary of results and conclusions from any studies performed with respect to such test. FDA, by regulation, would be required to set forth instances in which raw data is *not* required to be submitted. The agency would only be allowed to require raw data if it is necessary to address one or more questions directly related to the analytical and clinical validity. FDA would be required to issue an order within 120 days. For *moderate-risk* tests, prior to offering, the developer must submit	Low-risk tests that are included on a list to be developed by FDA are exempt from premarket review, along with other types of IVCTs previously discussed in the definitional scope section, in addition to tests within the scope of a developer's precertification order (subsequently discussed). For IVCTs that are exempt from premarket review, a detailed process is established that could subject them to premarket review – and ultimately removal from market – if FDA makes certain determinations, including that there is insufficient valid scientific evidence to support the analytical or clinical validity or there is a reasonable potential that such IVCT will cause death or serious adverse health consequences. *Application contents* - Prior to regulations requiring comparable information going into effect for IVCTs, applicants must submit information required pursuant to 21 CFR 814.20 (PMA regs) in their application. An application must include general information regarding the test, including a description of its intended use, an explanation regarding how the test functions and its performance characteristics, and a risk assessment, as well as information demonstrating compliance with any applicable mitigating measures, standards, and, except in the case of test platforms, QSRs. All applications must include valid scientific	Generally tracks FDA TA, though includes several noteworthy additions: Adds a requirement for FDA to issue guidance on exempting certain point of care tests from premarket review. Adds provisions in brackets that exempt collection articles and test platforms not previously approved by the FDA from premarket review of quality systems documentation and preapproval inspection. Such provisions also state that developers of such articles and platforms shall not be required to provide raw data in their submissions by default. Adds another bracketed provision exempting developers who choose to submit a test for premarket review that would otherwise be eligible for precertification from including quality systems documentation or raw data in their submission. The new provision also exempts them from being subject to a preapproval inspection in this instance. Adds a bracketed "Breakthrough" pathway with a note that legislative text will be supplied. Unclear how this would differ from priority review approach already included and subsequently discussed. Adds a bracketed "least burdensome" section.

	evidence that demonstrates reasonable assurance of analytical and clinical validity. Like for high-risk tests, applications must include a summary of relevant valid scientific evidence and the protocol and summary of results and conclusions from any studies performed with respect to such test. FDA may not require raw data from such studies to be routinely submitted and the agency, by regulation, must set for instances in which raw data *is* required to be submitted. FDA would be required to issue an order within 75 days. If FDA does not issue an order with 75 days, the IVCT may be legally marketed by the developer and shall be treated as having an approved application. For IVCTs that meet certain criteria, DAIA establishes a special review pathway that would allow for "approval with confirmatory postmarket obligations" (AWCPO). An IVCT would be eligible for this pathway if it is intended for a serious or life-threatening condition for which there is no approved or legally marketed IVCT with the same intended use ("unmet medical need test") or it is a moderate-risk test that demonstrates reasonable potential to improve the ability to identify, measure, detect, predict, monitor, or assist in selecting treatment for a disease or other condition (i.e., offers a "clinically significant advantage" over other	evidence from nonclinical laboratory studies involving the test, or in the case of a test platform or article for taking or deriving specimens from the body, with a representative test or tests covering all intended test methodologies that include the test platform or collection article, to support analytical and clinical validity, which shall include summary information for all supporting validation studies AND raw data for tests that are high-risk, cross referenced (references in its labeling the name or intended use of another medical product that is not an IVCT or is referend itself in the labeling of another product that is not an IVCT), first-of-a-kind (has an element or elements that differ(s) from the combination in any legally available test group), unless FDA determines otherwise, with raw data for all other tests available upon FDA request. For IVCTs for which clinical validity is included in the relevant standard, applications must include valid scientific evidence from clinical investigations with the test involving human subjects to support clinical validity, which shall include raw data for tests that are high-risk, cross-referenced, or first-of-a-kind, unless FDA determines otherwise, with raw data for all other tests available upon FDA request. To the extent the application seeks authorization to make modifications within the scope of approval, the application must include a change protocol that includes validation procedures and acceptance criteria for specific types of anticipated modifications that could be made to the test under an	

	approved or legally marketed IVCTs). FDA shall approve these tests if the developer submits an application demonstrating a reasonable assurance of analytical validity and *probable* clinical validity for its intended use and the developer agrees to confirmatory postmarket obligations and timeframes, which would be specified in the order and may include reporting requirements, and which would be required to be met in order for the approval not to lapse. FDA would be required to issue orders within 30 days for unmet medical needs tests and within 75 days for moderate-risks that demonstrate reasonable potential to offer a clinically significant advantage. For *low-risk* tests and rare disease tests, no premarket submission is required. Developers must notify FDA of the test name and intended use within ten days of first offering.	approved application. For an article for taking or deriving specimens from the human body, and for any IVCT that includes such an article, an application must include safety information as applicable, including but not limited to biocompatibility, sterility, human factors studies and user studies, and information regarding the types of tests that could be used with the article. For a test platform, and for any IVCT that includes a test platform, an application must include data, as applicable, to support software validation, electromagnetic compatibility, and electrical safety, or information demonstrating compliance with applicable recognized standards addressing these areas. FDA may on its own initiative or upon the request of an applicant refer the application to an advisory panel. The agency shall review, as promptly as possible but in no even later than [X] days after an application is accepted for submission and issue an order approving or denying the application, relying on the intended use included in the proposed labeling submitted by the applicant. An order approving the application may require conditions of approval and shall be published on the FDA website along with a summary of the data used to make the decision unless restricted from disclosure pursuant to another statute. Denials are subject to an appeals process. For first-of-a-kind tests, an order may impose	

		requirements for tests that fall within such a test group and shall indicate whether subsequent tests in that group may meet any applicable exemptions established in the legislation. FDA may, after providing due notice and an opportunity for an informal hearing, issue an order withdrawing approval if the grounds for approval are no longer met OR there is a reasonable likelihood that the IVCT would cause death or serious adverse health consequences.	
Priority Review/Provisional Approval		An IVCT may be eligible for priority review designation, review, and provisional approval or approval if the test provides or enables more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions compared to existing approved or precertified alternatives AND it is a test that represents a breakthrough technology for which no approved or precertified alternative exists that offers a clinically meaningful advantage over existing approved or precertified alternatives. Unless FDA determines it is otherwise eligible during its premarket review, an applicant must request designation for priority review and submit information demonstrating the test qualifies, which FDA will decide upon within 60 days after the receipt of such request. If provisionally approved (reasonable assurance of clinical validity and probable clinical validity), FDA will issue a provisional	Priority review same as FDA TA. Provisional approval concept not included.

		approval order that would include confirmatory postmarket obligations and timeframes for completion. Provisional approval expires on the date that is specified in the order, except that if an application for approval is submitted three months before this date, the date on which the FDA decides on the application. IVCTs that are provisionally approved must be labeled accordingly. FDA may, after providing due notice and an opportunity for an informal hearing, issue an order withdrawing provisional approval if the test no longer meets the relevant standard or the test presents an unreasonable risk to human health.	
Precertification	N/A	An IVCT is exempt from premarket review if its developer is precertified and the test is both eligible and falls within the scope of a precertification order that was issued to the developer and is still in effect. Entities could obtain precertification for one or more categories of tets. An IVCT is eligible unless it is a component, part, or accessory; a test platform; an article for taking or deriving specimens from the human body; software unless such software itself can perform as an IVCT; a first-of-a-kind IVCT; a test system for home use; a high risk test; or is intended as a specific type of blood component test listed in the exclusionary criteria. The only way for a cross-referenced IVCT or a DTC IVCT to be eligible is if FDA determines that eligibility is appropriate based on mitigating measures applicable to the test.	Generally follows FDA TA with several key differences: IVCTs that are first-of-a-kind, test systems for home use, high-risk tests, cross-referenced tests, or DTC tests are not eligible for precertification unless FDA specifically determines that a test group is eligible after a public process established in the Federal Register. While, as in the FDA TA, an application for precertification may not be broader than a single technology, it can now include multiple medical subspecialties. The representative IVCT must represent the highest complexity test to validate and run within the scope of precertification. An initial precertification order expires after two

		An application for precertification shall include a statement identifying the scope of the proposed precertification, which shall be no broader than a single technology (i.e., test method) and a single medical subspecialty (i.e., such as would be described by the combination of a test purpose and disease and condition); information on conformance with QS requirements; procedures for analytical and clinical validation; a notification for each IVCT that would be precertified and offered for clinical use upon issuance of an order; information concerning one or more representative IVCTs, including an explanation of how it adequately represents the range of procedures included in the precertification application. FDA shall, as promptly as possible, but in no event later than [X] days after receipt of an application, issue an order, which shall specify the scope of the precertification or deny the application and set for the basis of such finding. An appeals process is authorized for denials. FDA shall grant an application if there is a showing of reasonable assurance of analytical and clinical validity for all tests within the proposed scope of precertification; the methods used in or the facilities or controls used for the development of all IVCTs within the scope conform to QS requirements and, among other things, there is a showing that the representative IVCT meets the relevant premarket review standard. A precertification order shall expire on the	years. Subsequent renewals shall expire four years after the date the order is renewed. Applications for renewal must include information on a representative test that is different from any prior application and must represent a different medical subspecialty, if applicable. Not later than one year after the effective date and annually thereafter for a total of five years, FDA is required to submit a report to Congress addressing a number of issues relating to precertification.

		date that is two years after the date that such order is issued, except that if an application for renewal has been received no later than [X] days prior to the expiration, such order shall expire on the date on which FDA has granted or denied the renewal application. Temporary hold and withdrawal authorities are provided.	
Accredited Persons	For purposes of reviewing moderate-risk IVCT applications, FDA would be required to establish a process by regulation under which third parties could conduct the reviews at the request of the developer and, if FDA disagrees with the third party's conclusion, the agency would need to provide the developer with a written justification for such decision.	FDA will establish a program and issue clarifying guidance to accredit persons, such as non-Federal government agencies and qualified nongovernment organizations, to review applications for precertification and applications for premarket review and make recommendations to FDA with respect to such applications. Within 90 days of receiving such a recommendation, FDA will make a determination. FDA may also accredit persons to conduct inspections of IVCT developers.	Same as FDA TA
Modifications	Rules for determining when modifications to IVCTs would need to be submitted for approval prior to such modified tests being offered – in addition to rules for determining when FDA must only be notified of certain modifications – are established.	The holder of an approved application shall submit and receive approval of a supplement before implementing modifications to an approved test unless the modifications are included in and implemented in accordance with an approved change protocol OR the modifications do not change any of the elements that define a test group, do not change performance claims or safety, do not adversely affect performance, and do not cause an IVCT to no longer comply with applicable mitigating measures or restrictions. For modifications that may be made without submitting a supplement (other than labeling changes that are made to address a safety	Same as FDA TA

		concern, which must be reported within 30 days), the developer must include them in the next annual report required to be submitted for the test following the date on which the modified IVCT was offered for clinical use, including a summary of the analytical and clinical validity, as applicable.	
Post-market requirements	Obligations for developers would largely resemble current FDA requirements for IVDs, except adverse event reporting would be updated to limited individual submissions to those events that involve death or imminent threat to public health, and use quarterly summary and trend reporting for all other events, including malfunctions.	*QSR* - Developers must establish and maintain a quality system. A developer that operates its own CLIA-certified high-complexity laboratory where its tests are for use only within that certified laboratory, such a quality system must consist of design controls; purchasing controls, including supplier controls; acceptance activities; corrective and preventative action; and records. Separate requirements apply to high-complexity laboratories that distribute test protocols to other entities. *AER* – Within 5 days, developers must report to FDA whenever they receive or otherwise become aware of information that reasonably suggests that one their tests may have caused or contributed to a death or serious injury; has malfunctioned and the IVCT would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; and such adverse event cannot be directly attributed to laboratory error. Quarterly reports shall be submitted for all other adverse events. *Post-market surveillance* – FDA may require post-market studies as a condition of approval, a mitigating measure, or when necessary to meet the relevant standard or mitigate patient harm.	Same as FDA TA

		Corrections and Removals – Within 10 days, a developer or importer must report to FDA any correction or removal of an IVCT undertaken by such developer or importer if the removal or correction was undertaken to reduce the risk to health or to remedy a violation of the FDCA caused by the test which may present a risk to health.	
Grandfathering	Grandfathers all IVCTs that are first offered on a date that is 90 days or more prior to enactment and considers them legally marketed. Developers of grandfathered tests would be required to list such tests with FDA within 180 days of enactment. Summaries of available analytical and clinical validity evidence must be submitted within five years of enactment for non-reviewed, high-risk tests. If FDA determines that a grandfathered test presents an unreasonable and substantial risk of death or serious adverse health consequences when used as intended, or is being offered with materially deceptive or fraudulent claims, the test will be misbranded unless the develop takes certain actions within 120 days of the notice.	If an IVCT is grandfathered, it can be lawfully marketed and is exempt from premarket review, QS requirements, and labeling requirements (but not registration, listing and AE reporting requirements). An IVCT is grandfathered if it is not an approved or cleared medical device and was developed by a CLIA-certified high-complexity laboratory for use within that laboratory and was first offered for clinical use 90 days or more before enactment so long as it is not modified on or after the date that is 90 days before enactment in a manner that would make it a new IVCT. Each grandfathered test report template must contain a prominent statement that it has not been reviewed by the FDA. If a grandfathered test is modified but per the developer's analysis is done in a manner that does not cause it to be a new IVCT, documentation for such a determination must be maintained and provided upon request. Modifications to grandfathered tests that result in a new IVCT designation (test group, performance claims, non-compliance with mitigating measures, etc.) are no longer grandfathered.	Same as FDA TA but clarifies that for an IVCT to be grandfathered it must be performed in the same laboratory in which it was developed or by another lab within the same corporate organization that shares common ownership by the same parent corporation.

Transition period	IVCTs introduced by laboratories prior to three months before enactment will be grandfathered. No submission obligations will apply to such tests prior to the effective date of the regulations (i.e., five years after enactment). New regulations would be required to be promulgated within three years of enactment. Compliance would be required no later than two years after that (with some opportunity to take advantage of the new system one year post-promulgation).	Tests that were offered, sold, or distributed prior to enactment that have been regulated as medical devices will continue to be so regulated until the date of enactment [yet to be established] at which point they will be deemed to have been approved under the new IVCT framework. Subject to the transitional IVCT provisions (discussed below), IVCTs that were first offered after enactment but prior to the effective date are required to comply with device regulations. For tests with device applications pending on the effective date, FDA may continue to rely on the device authorities when taking action on such a submission. Transitional IVCTs are tests developed by a certified high-complexity lab for testing within that laboratory that are first offered during the period that is 90 days before enactment and the effective date. Such tests may continue to be offered until the effective date, though FDA can rely on device authorities if necessary to protect the public from a serious risk to health. Transitional IVCTs with premarket or precertification applications pending on the effective date may continue to be offered during the review. Test platforms that were purchased prior to enactment and have not been review by FDA may continue to be used by the purchaser for test development and clinical offering for 5 years after the date of enactment. Ay that point, any new IVCT that is developed and offered must be based on a platform that has been reviewed by FDA.	Same as FDA TA
