AdvaMedDx VALID Assessment Framework

To Facilitate Analysis of The VALID Act

On March 5, 2020, The Verifying Accurate, Leading-edge In Vitro Clinical Test Development (VALID) Act was introduced in the U.S. House and U.S. Senate. AdvaMedDx, with the guidance of the AdvaMedDx member Dx Task Force, has developed the VALID Assessment Framework as a tool to analyze the legislation. The AdvaMedDx VALID Assessment Framework:

- Identifies and describes the four highest priorities for IVDs as put forward in the December 2018 VALID draft; outlining additional policies of import.
- Explains the rationale for prioritization of each priority, i.e. how would it foster innovation? Reduce burden?
- Sets the criteria to analyze each of these priorities in The VALID Act, as introduced,
- Will assess equality of treatment for IVDs and LDTs in introduced bill.
- Will assess the potential impact of each priority.

BACKGROUND:

Overview of AdvaMedDx Priorities in Diagnostics Regulatory Reform

In general, AdvaMedDx Priorities for Diagnostics Regulatory Reform are for:

- A modernized, predictable and transparent risk-based diagnostics regulatory framework to which all developers of in vitro diagnostic tests and technologies – LDTs and IVDs – would be subject.
- The framework should recognize the unique characteristics of diagnostics.
- It should set forward clear regulatory pathways that would efficiently allow for developers of high-quality *in vitro* diagnostic tests and technologies to leverage their proven track record for smart, streamlined reviews, speeding innovative tests to providers and patients.

Overview of Diagnostics Regulatory Reform Legislation, The VALID Act

While borrowing many concepts from the Food, Drug, and Cosmetic Act (FDCA), the VALID Act, introduced in both the House and Senate, March 5, 2020, would establish a new regulatory framework under the FDCA for the review and oversight of all in vitro diagnostic tests (IVDs and LDTs) terming such in vitro clinical tests (IVCTs). The new framework would be separate and distinct from the medical device framework. It would not change or modify the Clinical Laboratory Improvement Amendments (CLIA) program. The framework aims to assure that IVCTs on the market provide a reasonable assurance of analytical and clinical validity.

Under VALID, based on risk and other IVCT characteristics, IVCTs would be subject to one or more pathways that include:

- Exemption: most “low-risk” IVCTs would be example from review, but required to notify/register;
- Technology Certification: IVCTs developers could choose the voluntary pathway of Technology Certification for review of IVCTs or suites of IVCTs, allowing introduction of new tests and modifications of tests within the scope of the Technology Certification. “High-risk” tests without mitigations, first of a kind, instruments and other categories of IVCTs would be excluded from this pathway under the VALID Act as introduced;
- Special Premarket Review: IVCTs that are not eligible for Technology Certification and are not high risk, cross-referenced, or first of a kind could go through this pathway, which would not require submission of raw data and would allow prospective change protocols.
- Full Premarket Review: IVCT developers with high-risk tests, first of a kind IVCTs, or cross-referenced diagnostics would be subject to this full review, including submission of raw data. Prospective change protocols would be permitted under this pathway.

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TOP PRIORITIES								
Applying a Risk-Based Framework	VALID uses risk as a key characteristic for determining review pathways for in vitro diagnostic tests whether LDT or IVD (referred to in the VALID draft as in vitro clinical tests, or IVCTs); not sole criterion.	**Highest**	Risk should serve as dominant determinate for IVCT regulation. A clear, predictable framework would incorporate appropriate review criteria and processes based on product benefit-risk balance that enables industry to readily understand regulatory category and the process to bring a product to market.	• Predictable framework with clear criteria for determination of high risk, high risk with mitigating measures, and low risk to enable predictability for IVCT developers on what IVCTs are subject to FDA review based on risk without automatic exclusions. • Associated, predictable regulatory pathways that are predominately determined by risk, subject to clear, consistent submission review criteria. Instruments that are currently low-risk or otherwise exempt from premarket review should maintain that status. • Clear risk-based patient and public health-focused criteria and procedures for changing the regulatory category or the		• Clarifies IVCT with MM is not high risk, but high risk definition tweaks need to be assessed (p. 9-10) • Definitions high risk, low risk, and MM have been tweaked and need to be evaluated (pp. 9-15) • Special pathway now clearly delineated; but needs clarification for certain test types (pp. 58-59). • Implies FOAK tests that are not high risk qualify for special pathway but process for	**03/10/20 Sub Team Assessment Meeting:** • Not solely a risk-based framework in light of automatic exclusions. • VALID adopted proposed language that IVCT is based on its own risk in component section but not elsewhere. Sub Team recommendation that we walk an accessory through the paradigm established by the bill to determine how the accessory would be regulated.	•

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				submission requirements for an IVCT or for revoking an exemption for a particular IVCT.		determination is unclear and regulatory pathway designation process is largely unchanged from draft (p. 59; pp. 105-107) • Review timelines outlined, based on a "refuse to file" period plus a review period (p.58/60); some clarifications needed • Cross-referenced test concept still used, with slight narrowing but remains ineligible for Tech-Cert (p. 8) (note also treatment of Cross-Referenced tests for humanitarian use, p. 40).	• IVCT definition: Ensure that by exempting something that is currently regulated as an IVD from definition of IVCT that it may be moved into device definition and be regulated separately from IVCTs. • Analysis on review timelines conducted (by Nate Brown, Akin Gump) to be shared with Sub Team. Movement from current fifteen days to 60 days for RTA. A sixty-day RTA for a 90-day timeframe does not make sense. RTA	

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							should be purely administrative and should not add time to overall review time. • IVCT definition's inclusion of component problematic since IVCTs would be subject to quality systems. • Need for basic process to move in and out of the submission pathways. Need to bolster language exclusions from exclusions, e.g., if well- understood etc. any of the members can be exempt.	

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							• As an example of this point and need for such a process to move across submission pathways, language on page 58-59 of the Bill regarding IVCTs eligible for special pathway needs to be clarified for predictability. We believe this is a question for guidance and implementing regulation as need for flexibility. • Gap with FOAK: Definitional focus on indications for use drives too many IVCTs into FOAK • Gap with cross-referenced:	

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							Definition is too broad and brings in too many IVCTs, e.g., monitoring IVCTs. Elements so detailed any minor change now new IVCT, e.g., new population. Move from general to specific indication e.g., *h pylori* previously would not trigger a new submission. Will need standard for invoking exception from exception of rare IVCTs; should not be on ad hoc basis. • Gap: DTC: We continue to believe it should not be automatic but	

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							should focus on intended use. • Gap: Prescription home use: We continue to believe it should not be automatic but should focus on intended use. • Possible opportunity provided with public health exemption to push out IVCTs without clinical claims? **03/19/20 Sub Team Assessment Meeting:** • Sub Team consensus to revisit our redlines, continue to recommend	

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							changes in this definition. • Definition of 'well characterized' utilized by the AdvaMed MDUFA sub team would be useful for the VALID Regulatory Sub Team to see for VALID assessment. • Group recommended continuing to push for our previously offered definition of mitigating measures. **04/01/2020 SUB Team Assessment Meeting:** • 587F Regulatory Pathway Redesignation – Group discussed	

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							587F relative to Application of Risk Based Framework. • Group consensus that 587F provides a necessary ability to FDA to 'reclassify', but that we will continue to push to remove the automatic exclusions. • Group discussed is there a way to address the definition of high risk for Direct to Consumer (DTC) tests and way to remove the auto exclusion. • 587F speaks to both redesignation and revoking. Group felt need for additional	

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							safeguards for both with heightened safeguards for revocation. • Group had process questions – Is a developer required to go with the 587F process if it is an IVCT where there is ample evidence that 'high risk' is mitigated (e.g., exceptions in definition of 'high risk' in VALID on page 10). Need understanding of how well-characterized products and mitigating measures (MMs) may help maintain what we currently consider	

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							Class II/moderate risk category. • Group recommended consider an approach where any IVCT regulated as Class II at the time of enactment would be deemed to be well-characterized pursuant to VALID. • Clarity needed on categorizing a product that is currently considered 'well characterized', moderate risk product, how to address where these fall in VALID pathways. Would everything currently Class II be deemed	

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							well characterized. Group proposed this would likely need to be discussed with FDA. • Group looking at if mitigating measures as defined in VALID are equal to current Special Controls • Keep focus on the process (587F) as it applies to truly novel IVCTs. • Group noted positive aspects of a 587F process under VALID as proposed could be that currently PMA IVCT or Class II IVCT may be able to move to a lower category.	

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							• Group suggestion that individual members may want to run their own products through and see where they end up.	
Technology Certification (formerly known as Precertification)	Voluntary pathway for IVDs or LDTs (collectively referred to in VALID as In Vitro Clinical Tests, or IVCTs) test/suites of tests allowing introduction of new tests and modifications of tests within the scope of Technology Certification excluding high-risk without mitigations.	**Highest**	If sufficiently flexible, could provide significant review efficiency for IVD test developers and appeal to laboratories and academic medical centers. Intended to serve as core pathway in VALID framework to provide efficiency in review for majority of tests subject to review.	• Scope of eligible tests and entities; fully risk-based approach; elimination of automatic exclusions. • "Technology" should be basis for determining the scope of a Technology Certification for a suite of tests. • Technology Certification processes fully defined, clear, predictable, and efficient for obtaining Technology Certification and renewal and appeals. • 3+ year duration of Technology Certification		• Scope is tied to technology (pp. 14-15, 86) • Statutory exclusions: instruments, specimen receptacles, components, blood-related, FOAK, home use, high risk, cross-referenced, and DTC (pp. 83-84). • FOAK, home use, high risk, cross-referenced, and DTC IVCTs can be made	**03/10/20 Sub Team Assessment Meeting:** • Several caveat words, e.g., "not similar" that would allow to advocate for specific cases. • Unclear what is meant by single based technology. Questions surrounding list of technologies. VALID Regulatory Sub Team generally agreed that list is helpful to show that	

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				• Appropriate scope and process for allowable modifications under a single Technology Certification order without additional review by FDA.		eligible via regulatory pathway designation process (p. 84). • Public docket, public meeting, and guidance requirements post-enactment (pp. 84-86). • Application elements described (pp. 86-89). • Duration of original certification and renewals is up to 4 years (pp. 93-94). • Review timeline is 90 days from receipt, subject to mutual agreement to extend; FDA must also identify deficiencies within 90 days (pp. 89-90).	FDA is thinking of technologies broadly. • Sub Team recommended an exercise of running specific IVCTs through first part (17(A)) of definition of technology. We could then pursue a listening session with FDA to discuss those examples. • Some of the examples on the list, e.g., "immunoassay," are extremely broad. • If there is a list included, noted that technologies are missing from the list of technologies, e.g., image analysis	

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						• Allowance to use approved test as representative test for certification (p. 51).	• Questions raised about "any other technology as the Secretary deems appropriate." Possible proposed addition of language "reasonably appropriate for scoping out certification" to clarify that this would expand and not narrow. • Possibility of recommending that FDA should issue guidance to address definition of technology, "which could include…." • The VALID Regulatory Sub Team discussed whether "energy	

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							sources" apply to IVCTs and decided that it is at least plausible for an instrument (which is not eligible for technology certification) or software, but might warrant additional discussion. • Discussion of interplay between Replacement Reagent and Instrument Family Policy (RRIFP) and technology certification. • Sub Team unclear whether first of a kind would be eligible for technology certification. Group	

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							believes it would be eligible if mitigating measures. • Content of Tech Cert, e.g., acceptance criteria, needs additional evaluation and discussion.	
Modifications Outside of Technology Certification	FDA and IVCT test developer agreed upon change protocols during review, allowing modifications w/in protocol to be made without agency review.	**Highest**	Clear, predictable, flexible approach to modifications, such that a change protocol policy would allow modification to be made within the protocol avoiding additional FDA review.	• Review of only significant modifications (for example clinically meaningful changes). • Specimen/sample type changes within a specified type should not subject to submission and review as a modification unless such changes are clinically meaningful. • Broad applicability of change protocol policy outside of Technology Certification. • Scope of individual change protocol.		• Modified test is a new IVCT if change affects AV/CV, no longer complies with MM, or affects safety (for specimen collection article); but excludes certain software updates, certain labeling changes, extends specimen stability, or is within a change protocol (pp. 43-44).	**03/10/20 Sub Team Assessment Meeting:** • Should be new IVCT if <u>significantly</u> affects AV/CV. Perhaps bring in clinically meaningful. Other potential remedy would be to only make it a modification if adverse impact (positive impact	

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						• Modifications that do not require a supplemental submission: those within a change protocol; do not change the AV/CV, the intended use, or the safety of the specimen receptacle; or labeling changes to address a safety concern (pp. 66-67). • Modifications under a change protocol are submitted in an annual report (p. 68).	would not be modification). • Inconsistency between statement that not new IVCT if labeling and p 60 that includes a contraindication • Specimen was noted generally as a win. • **Additional Notes from Deep Dive, Specimen Receptacle -** Sub Team specimen receptacle deep dive analysis noted two additional items to be tracked for redlines - Definition of specimen receptacle (587(16)) and Test Design and Quality	

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							Requirements (587J(a)(3)): - Definition does not include specimen collection device. 'Taking' is missing from definition, should be added back in. Unclear if is this was intentional deletion or not. This definition does not track to original language and comments provided to the VALID. - Specimen Receptacle Test Design and Quality Requirements (587J(a)(3)) - Group will revisit quality requirements. Further comments	

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							and language revision needed. • Gap: Site changes – all would be modifications requiring a submission. • Should not need to report changes made pursuant to change protocols • Change should be revised to within scope of change protocol. Currently, it must be within the scope of approval. • Annual reporting for all changes is very problematic. The volume of changes made is huge and no patient safety difference between	

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							manufacturer and laboratory making changes. If no patient implications it is not an issue, but if patient safety, then both laboratories and manufacturers should have to report. As is, FDA does not have bandwidth to review the PMA annual reports and that is only a small portion of submissions. • Possible addition of language to explicitly state that change protocols would be available would all IVCTs that	

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							are ineligible for tech cert. **03/19/20 Sub Team Assessment Meeting:** • Group recommended continuing to push for our definition of clinical validity - revisit the definition of clinical validation (CV) as proposed in 10/08/19 definition document e.g., consider clinical utility. Consider the redlines previously offered for CV. • Analytical Validation (AV) definition - Group decided that we can probably live with this definition. There was discussion of	

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							whether it was too subjective for the laboratories (use of the term 'sufficiently' is subjective) but the group is ok with it. **04/24/10 Sub Team Assessment Meeting:** • Definitions for Clinically Meaningful and Clinically meaningful impact not in VALID. Group agrees we must include. We would attempt to prevent a subjective interpretation of clinically meaningful. Previous redlines were offered 12/18/19 – we will	

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							consult those and make proposed redlines. • Intended Use – there is not a lot of language in bill around intended use, there is more focus on indications. Refined definition may be needed – look at and recycle prior AdvaMedDx Comments on intended use. May want clarification around what constitutes 'clinically meaningful' changes for indications • P. 60 requirement for amendment or supplement – Need	

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							clarity on language in (A) regarding *'could reasonably affect safety'*. Suggest change to could 'adversely affect safety'. The interpretation of 'reasonable' is open. See if changes can be made to add clarity. • Labeling changes to be made to address safety concern – does this requirement conflict with warnings and statement of contraindications in (B), P. 60 of VALID). • VALID did not address modifications of	

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							tests developed by others. • Group recommends all companies run their respective products through the proposed process for modifications and see how they fall out. • Are there gaps in the proposed modification process that may not work? Important to consider how making potential changes may affect status of a product: – Is there possibility a product will get kicked out of an exempt status, or	

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							ability to utilize tech cert because of certain types of changes/ modifications?	
Instruments (Platforms)	Currently, low-risk instruments/platforms are exempt from review. Per VALID, instruments would be subject to "abbreviated review" and not eligible for Technology Certification.	**Highest**	VALID should foster efficiency, maintaining current exemptions.	• Instruments (platforms) that are currently low-risk or otherwise exempt from premarket should maintain that status • Maintenance of current exemptions and treatment of instruments (platforms) such that review encompasses appropriate level of quality system documentation. • Instruments (platforms) would be eligible to undergo Technology Certification. • Ensure Replacement Reagent and Family Policy is still allowed under VALID.		Instruments are subject to special review pathway (pp. 58-59). As long as one version of the instrument is approved and certain criteria are met, other versions in the Instrument family need not be reviewed (p. 11 & p. 49). Transition period for marketed instruments: 5 years from enactment (*note that this needs to change given new delay of 3-4 years between*	**03/10/20 Sub Team Assessment Meeting:** • Essentially codifies Replacement Reagent and Instrument Family Policy (RRFIP). • Port over IVCT (assay) that has been approved per VALID, including those that went through tech cert. • Potentially revisit our language regarding device master files. • Definition of instrument family	

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						enactment and effective date) (p. 214).	not clear where tolerance level and signal detection. Tolerance level may be too broad. • Want to ensure that FDA honors the policy; is there language we can add to achieve this goal? • Need consistency in language: Platform appeared in a few instances. • Need to clean up transition period to make consistent with new transition provisions. • If instrument has been cleared as part of existing clearance of IVD, that	

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							clearance should also port over. • Sub Team still discussing whether to challenge fact that certain currently exempt instruments would have to go through FDA.	
ADDITIONAL PRIORITIES OF IMPORT (Tiered High, Med, Low)								
"Claw-Back"	FDA has authority to remove from the market all tests (including grandfathered LDTs) except those that have been subject to an FDA full premarket review.	**High**	Concern with broad authority that could allow FDA to inappropriately "claw-back" an IVD approval. As written, VALID has a single "claw-back" provision that applies to three very different situations: FDA	• Provision(s) included that will place appropriate limits on broad FDA ability to "claw-back" IVCTs marketed under FDA authority. • Claw-back" authority should mirror existing authority for exempt, 510(k) and PMA		FDA has "clawback authority" for most exempt tests, based on lack of VSE, deceptive claims, or reasonable possibility it will cause serious adverse health consequences (pp. 20-21) (*note reference is to*	CLAWBACK ASSESSMENT TBD **05/21/20 Sub Team Assessment Meeting Deep Dive analysis on specimen receptacles application of clawback provision**– Question was posed if most specimen	

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			cleared/approved/exempt IVDs; IVCTs following VALID implementation; and LDTs grandfathered under VALID.	products without fear of arbitrary removal from market.		*587B but likely should be 587A*). Process for FDA to request information and for continued marketing during agency review of response; process for FDA to issue order ceasing distribution and to hold hearing (pp. 22-27). A regulatory pathway redesignation process allows FDA to revoke exemptions or requirements or to grant exemptions from review or Tech-Cert eligibility based on new information or the establishment of MMs; provision took some of our suggestions but still lacks full APA process (pp. 105-07).	receptacles are Class I today and exempt from PMA- is the abbreviated pathway too high of a burden??	

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Point of Care	VALID would require FDA to issue guidance indicating categories of point-of-care technologies that could be exempt per VALID.	**High**	Currently, even low-risk POC diagnostics cannot be exempt from 510(k) review due to outdated regulation.	• Sufficiently facilitates introduction of innovative point of care tests. • Provide for appropriate regulatory framework around POC. • Not deemed high risk due to POC; removal of .9 limitations. • Address need to define Near-Patient testing.		FDA to issue guidance on new types of POC tests to be exempted from review, on year after enactment (p. 35).	**03/19/20 Sub Team Assessment Meeting:** • Need to ensure definition clarity. • Review against criteria to assess current language which is throughout sections of VALID. • ADDITIONAL ASSESSMENT TBD - Sub Team Member Volunteer will conduct and provide a deep dive analysis of POC to the group.	
Administrative and Due Process Protections	Need for FDA to abide by existing due process and procedural protections, including ones for appeals. VALID proposes removal of many of those protections.	**High**	Without due process and administrative procedural protections, companies would not have recourse if FDA makes an unfavorable decision.	• Reinstate procedural and due process protections.		Some process enhancements in line with our comments; but many deviations from APA and other process protections.	ASSESSMENT TBD	

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CLIA Waiver	Not addressed in VALID; does not alter existing CLIA Waiver authority.	**Mid-High**	Desire for single submission and study for product approval and waiver. Currently duplicative and burdensome processes for *in vitro* diagnostics used in a CLIA-waived setting (*in vitro* clinical tests – IVCTs under VALID)	• Establishes a regulatory standard that enables developers to obtain both regulatory approval and CLIA waiver through a single submission. • Sufficiently facilitates introduction of innovative CLIA-waived tests. • Provide for amendment of FD&C Act or improvements within existing law. • Ensure 21st Cures CLIA Waiver language transfers to VALID.		Not addressed.	**03/19/20 Sub Team Assessment Meeting:** • Legislation still lacks comprehensive framework to advance POC and CLIA-waived tests. For instance, how is a test that goes through Tech Cert categorized? • Sub Team Member Volunteer will conduct and provide a deep dive analysis of CLIA Waiver to the group.	
Transition Periods	For those tests – IVCTs - requiring review under VALID, the length of time allowed to transition over to new requirements.	**Mid-High**	Transition period needed to allow manufacturers to adapt to new scheme.	• Defined and appropriate period for transition.		Effective date will be 4th FY after enactment. Series of guidances and regulations to be issued by FDA during that period.	**03/10/20 Sub Team Assessment Meeting:** • Drafting errors: transitional (ones introduced after enactment). Up to 90 days of effective	

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						Cleared and approved devices will be deemed approved under VALID; IDEs will also be converted automatically (pp. 213-14). Pending submissions as of effective date will be reviewed based on existing device framework. (pp. 207-15)	date or up to effective date for transitional IVCTs. • Potential to lose time for preparing submissions because guidances will not be ready • At same time would have more time to get submissions in - might be able to make strategic decisions surrounding product pipeline. • This is new language with new details that will need to be further evaluated. • Missing provision to prevent incentive to quickly bring IVCTs to market ("dumping" of	

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							products on market).	
Collaborative Communities for IVCTs	VALID provides for collaborative communities to provide recommendations on development and regulations of IVCTs.	**Mid**	Current industry experience with collaborative communities related to other topics has not been favorable.	• Transparent and well-defined process for use of collaborative communities with appropriate provisions to prevent use to set regulatory policy and requirements. Process should provide for appropriate protections for industry and level of operating independence from FDA.		Added some level of independence and transparency (took some, but not all, of our suggestions); allows FDA to participate but not establish (pp. 171-73).	**04/01/2020 Sub Team Assessment Meeting:** • Group acknowledges we may not be able to remove Collaborative Communities (CCs) in VALID, therefore group suggested the following additional safeguards to ensure transparent and well-defined process: • Ensure all stakeholders have opportunity to provide input; Ensure that FDA accepts the work products proposed by a CC. For	

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							example, ensure a process for stakeholders to provide input/comment on recommendations a CC has made to FDA (similar to existing public meeting process). This could provide process to allow comment from those stakeholders who have not been directly involved in the CC. • Criteria the group suggests for CCs: What are the limits for CCs; What determines the need for a CC; CC length of life; Consider when a CC	

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							would be useful for industry, for example – determining performance criteria.	
Data Requirements	The level of data required for full review under VALID.	**Mid**	Analyzing and packaging raw data is time intensive.	• Streamlined and least-burdensome data requirements; should minimize the amount of raw data required to be submitted to FDA.			ASSESSMENT TBD	
Grandfathering	Would exempt LDTs on market from FDA review and Quality System requirements in future. Includes authority for FDA to remove tests from market. Would require any significant modification to a	**Mid**	Grandfathering LDTs provides for transition into new framework.	• After assessing in the context of the overall package, is the grandfathering provision acceptable. • Assess categories of high-risk products when considering grandfathering provision. • Grandfathering provision should allow FDA to review and remove from market tests with demonstrated challenges.		Qualifying LDTs with labeling disclaimer are grandfathered if offered before date of enactment (pp. 30-32) R&L by one year after new Notification system is established; appears to mean no notification until after effective date (p. 118).	ASSESSMENT TBD	

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	grandfathered test to be reviewed by the agency.			• Significant modification to grandfathered tests should be subject to review.		Significant modifications subject to review (p. 33) "Transitional IVCTs" are those first offered between enactment and 90 days prior to effective date (*or perhaps up to the effective date; the bill appears to have conflicting language*); may stay on the market but must submit application within 90 days of effective date (pp. 210-13). FDA has "clawback authority" for a test that lacks VSE, has deceptive claims, or reasonably possible it will cause serious adverse health consequences (pp. 20-21).		

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Appropriate Regulation of Accessories	Ensuring the regulation of accessories is based on the risk of the accessory not the parent device.	**Mid**	The 21st Century Cures Act included provisions that an accessory should be regulated on its own risk as opposed to the risk of the parent. This is particularly important if the risk of the parent is higher than the risk of the accessory.	• Regulation of accessory should be based entirely on risk of accessory.		Not addressed (although increased focus on developer's intended use may be somewhat helpful.	ASSESSMENT TBD	
Least-Burdensome Approach	Current law requires that FDA accept minimum required information to support determination that relevant standard or regulatory requirement has been met.	**Mid**	Fundamental aspect of current law that provides a legal mechanism to challenge FDA when it is not adhering to "least-burdensome principles."	• Explicit language stating that FDA shall follow a least-burdensome approach, similar to current law.		Contains explicit language; but did not take our suggestion to reference use of device master files (pp. 74-75).	**04/09/2020 Sub Team Assessment Meeting:** • Applies to all area per guidance. Can we make it specific to IVCTs and make it clear what constitutes least burdensome. • Currently the concept of least burdensome is sprinkled throughout VALID vs. containing a section about what	

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							constitutes least burdensome as part of the legislation. • VALID may reflect FDA perspective of least burdensome vs industry perspective so may want to consider if in VALID can add aspects to have more teeth in it. • The question is what amount of change is desired for this policy? Could we use the language for least burdensome that is found on pages 74/75 of VALID in (j) put this up front in the bill and say it applies to the application of least	

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							burdensome for all sections?	
Transition from Quality System Requirements to ISO 13485	FDA has stated plans to issue proposed regulation to transition the QSR to ISO 13485, which we would like to see reflected in VALID.	**Mid**	Many companies are global companies. Having to meet only one quality system instead of multiple ones would vastly reduce costs.	• Inclusion of ISO 13485 in VALID to promote global harmonization; VALID should discuss evolution of the current QSR (Part 820) to 13485.		FDA to consider "whether and to what extent" int'l harmonization "is appropriate" in promulgating QR regs (p. 122).	**03/19/20 Sub Team Assessment Meeting:** • There is a lack of parity as there is not the same regulatory oversight for the same activities, and there should be. • Disparities of QS requirements – example - When a laboratory makes a test kit, the laboratory should be subject to shipping, distribution and other requirements. To do otherwise risks contamination. • Ensure QS part flexibility and	

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							harmonization with ISO13485. • Sub Team Member Volunteer will conduct and provide a deep dive analysis of QS to the group.	
Labeling	IVD companies are presently subject to exhaustive labeling requirements. VALID provides descriptions for what constitutes IVCT labeling.	**Mid**	Outdated and extensive labeling requirements are costly to companies and confusing to patients and healthcare providers.	• Reduction of confusing and/or outdated labeling requirements, (e.g., Rx-only). • VALID should include electronic labeling provisions.		Labeling change to address patient or user harm exempt from modification definition (p. 45); labeling change to address a safety concern exempt from review (p. 67). E-labeling not really addressed other than in misbranding exception (p. 180)	**05/07/20 Sub Team Assessment Meeting – Labeling Deep Dive:** • Group discussed if should consider alignment with ISO standards (18113 series and 15223) for labeling content and use of symbols (Eliminate 'For US' requirements of packaging content). • VALID page 127 – 587K(a) Labeling Requirements – *…test shall bear or*	

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							be accompanied by…suggestion that language should be changed, but group points to language ok per case law. • Page 127, 587K(d) – LDT exemptions from requirements. Group believes should not be isolated to LDTs, e.g., posting on website should apply to all. Include Electronic labeling and allowance to include website and/or other sources. Example used was for - instrumentation manual electronically available.	

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							• Page 128 – Content-(i) out of sync - CTIS already includes labeling, therefore this is duplicative info and will delay labeling approval. • Page 133 – (f) Guidance - Need strategic approach here, detailed statute that contains clarity for labeling requirements vs. guidance. Group concern 'standardized' language may point to Structured Product Labeling (SPL) as required by CDER. Need to determine if this is intent. Discussed	

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							adding a provision to cover e-labeling points.	
Adverse Event Reporting	Includes malfunction and adverse event reporting.	**Mid**	Adverse event reporting is a hallmark of any successful postmarket vigilance program. Presently, LDTs are not subject to FDA adverse event reporting requirements.	• Adverse event definitions and timeframe: Includes adverse event reporting that mirrors current requirements for IVDs, applied to all IVCTs. • Ensure quarterly malfunction reporting without unnecessary restrictions		• Adverse event reporting is different	**03/19/20 Sub Team Assessment Meeting:** • The group discussed the need to closely evaluate and to crosswalk with current requirements. • P. 135, Line 1 - The group prefers the term contributed to patient death vs. 'involves'. • Quarterly reporting content requirement needs to be reviewed. **05/07/20 Sub Team Assessment Meeting – AE Reporting Deep Dive Analysis:**	

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							• Section 587L – page 134 (b) – Adverse Event Reporting Requirements: VALID Language is '<u>Reasonably suggests</u> IVCT <u>may have caused or contributed</u> to death or serious injury'. Group suggests consider if this language (different from current in FD&C Act) will assist us or do we want to make changes? Current language in FD&C Act is well understood. • Definitions page 135 – *in vitro clinical test error* - Recommend deleting 'includes"	

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							and "that" from definition of IVCT test error. Pulling out 'includes' and 'that' – will track better to definition of a test error. Group believes current definition in VALID is too broad and recommended deletions will narrow the definition. • Suggestion to consider deleting first "or" in Section 587L(d)(3)(A(. Discussion to take out or and potentially redline language. Determine if FDA is mixing in any potential for serious	

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							injury. Rewording section or taking out language to ensure must meet conditions for negative clinical impact. Issue is to determine if they are mixing in 'potential' for serious injury. • Reports: [Section 587L(c)(1)(A)] - Individual event reported 5 calendar days to report event from receipt or awareness that reasonably suggests the adverse event involves a patient death. Change 'involves' to 'contributed to'	

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							• Reports - Time range of 5 days is less favorable; reduced time to report and broader scope. Recommend 30 days, not 5 days. • [Section 587L(c)(1)(B)] - 5 calendar days to report event from receipt or awareness. Less favorable; reduced time to report - current time frame starts at remedial action not date of awareness. Agreement to push for more time, Consider changing 5 days to 15 or go back to original	

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							language in FD&C Act. • Quarterly Reports - [Section 587L(c)(2)] – Timeline to implement would be important – consider adding a provision to allow IT/developers 18 months from final specifications to implement IT system/changes. • Filing not an admission of liability – should this be clearly stated in statute?	
Publicly Accessible Listing of Comprehensive Test Information	Online, publicly accessible database proposed to provide information about IVCTs.	**Mid**	Information and process should mirror that provided in Device listing.	• Appropriate amount of information should be available.		CTIS to include reg pathway for IVCTs w/ same IFU; R&L info; AE reports; recall info; other info. Will provide-	**03/10/20 Sub Team Assessment Meeting:** • Potentially too much information	

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						submission portal (pp. 174-75).	required in current format.	
Notification	Proposed notification requirements (intended to be like listing for IVCTs) broader than current device listing requirements.	**Low-Mid**	Information and process should mirror that provided in Device listing.	• Notification requirements should mirror current listing requirements.		R&L process conceptually similar to current process; but info elements include brief summaries of AV/CV, MM, representative labeling, etc. (pp. 112-21).	**04/09/20 Sub Team Assessment Meeting:** • Process concern - providing all the labeling is problematic. Group wonders if FDA is trying to make this more like the SPL (Structed Product Labeling) system used in FDA for drugs. Concern is that type of system is too far reaching. VALID Language needs to be tight enough to keep FDA from going in that direction. • Need clarification on process - Almost all the required info	

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							is included in labeling. Can a label be provided into the system rather than having to enter all info in the system individually in fields.	
Breakthrough	Designation allowing for priority review of, and increased interaction with FDA staff and senior management regarding, IVCTs which meet specific eligibility requirements. Concept consistent with existing breakthrough provisions for medical devices.	**Low – mid**	Successful program has sped innovative devices to market. The increased interaction opportunities have been particularly valuable to industry.	• Inclusion of breakthrough pathway modeled on current law.		Breakthrough pathway modeled on current device breakthrough designation with same tools and timeline (60 days); guidance to be issued within one year of enactment (pp. 76-81). Appears to apply to all review pathways. Note transition of breakthrough designations may need to be addressed.	ASSESSMENT TBD	

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Appropriate Regulation of Components	Ensuring a component subject to further development does not become subject to further review.	**Low - Mid**	Currently, components (subject to further development) reviewed as part of finished device.	• Component is removed from the definition of IVCT. • Component definition is in the language and language does not create a systems approach.		Page 29	**03/19/20 Sub Team Assessment Meeting:** • Definition of component - No definition in VALID. Specific examples would be helpful to ensure. Group agreed to look at previously offered revision of definition in context of current language. Additional issue is accessories are not in VALID. • Group agreed that this is an area that continues to need refinement as there are several questions, including the interplay between the language on page	

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							29 and page 4 of VALID and what constitutes an "integral component." • Sub Team Member Volunteer will conduct and provide a deep dive analysis of Components to the group.	

Other:

- Emergency Use provision would codify FDA's recent guidance allowing CLIA labs, in the event of a public health emergency, to use a test pending submission of an EUA, with no time limits; a similar allowance is not available to manufacturers (pp. 27-28). Assessment - The group discussed a list of proposals provided by Roche. Language proposed for Sample Access, Real World Evidence, Clarification of CLIA Waiver for EUA Tests and Ongoing availability of EUA tests. (Language included in alternate legislative proposal April 2020).
- Codification of an informal feedback/pre-submission process.
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*__Note: VALID Regulatory Sub Team Assessment Meetings Dates: 03/10/2020; 03/19/2020.__ As part of March 19 Assessment meeting, the VALID Regulatory Sub Team agreed for individual Sub Team Members to each take on individual priority topic assessments and provide these 'Deep Dive Assessments/Analysis' back to the team for group assessment at the future Sub Team meetings.)