DxCONNECT MARKET PLACE QUALITY ASSURANCE: PRODUCT SELECTION & EVALUATION CRITERIA

CURRENT AS OF: 27 JAN. 23

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Contents

Abbreviations

APEC	Asia-Pacific Economic Cooperation
CFR	Code of Federal Regulations
CVD	cardiovascular disease
DxCM	DxConnect Marketplace
EDL	Essential Diagnostics List
EUA	Emergency Use Authorization
EUL	Emergency Use Listing
FDA	Food and Drugs Administration (USA)
GHTF	Global Harmonization Task Force
GHWP	Global Harmonization Working Party
HIV	human immunodeficiency virus
IFU	instructions for use
IMDRF	International Medical Device Regulators Forum
ISO	International Standards Organization
IVDs	in vitro diagnostics
IVDD	EU In Vitro Diagnostic Medical Devices Directive
IVDR	EU In Vitro Diagnostic Medical Device Regulation
LMIC	low- and middle-income country
LSIF	Life Sciences Innovation Forum
MDSAP	Medical Device Single Audit Program
NCD	non-communicable disease
NRA	national regulatory authority
NTD	neglected tropical disease
PAHO	Pan American Health Organization
POC	point-of-care
POCT	point-of-care test
PQ	prequalification
QMS	quality management system
R&D	Research and development
SOP	standard operating procedure
SRA	stringent regulatory authority
TGA	Therapeutic Goods Authority (Australia)
TGS	Technical Guidance Series
TPP	target product profile
UHC	universal health coverage
WHO	World Health Organization

General considerations

From research and development (R&D) to delivery, FIND has been actively involved in identifying and unblocking the bottlenecks that prevent the development of a healthy diagnostics market in low- and middle-income countries (LMICs). Unlocking the value of diagnostics in primary healthcare settings requires the availability of rapid, robust, user-friendly, affordable and accurate diagnostic tools, including self-tests and point-of-care (POC) tests, as part of an integrated health system that links diagnosis to care.

The DxConnect Marketplace (DxCM) was created by FIND to bridge the gap between manufacturers that offer innovative, affordable, quality-assured products and the buyers that wish to bring these products to their local market.

To enable FIND to source products for DxCM, a robust and inclusive quality assurance (QA) criteria was developed. This QA criteria provides a dedicated process for assessing the quality of products that may or may not have World Health Organization (WHO) prequalification (PQ) or stringent regulatory authority (SRA) approval. The DxConnect Marketplace QA criteria outlines a framework for the selection and evaluation of diagnostic products for inclusion in the DxConnect Marketplace. In accordance with FIND's Global Access Policy, the DxCM QA criteria commits to ensure fit-for-purpose, relevant and affordable diagnostics and to maintain optimal quality standards, in the belief that product and service quality should not be compromised despite aiming for the lowest cost of diagnosis to patients in need.

FIND's QA Criteria is outlined in two distinct sections:

1. Diagnostic product selection criteria
2. Quality Assurance Process for inclusion on in the DxCM

A Supplier is only authorized to list products in the DxCM once it has been selected, assessed and approved by the product selection and quality process established in this guidance.

Scope

1. This criteria covers all durable and non-durable diagnostic tools/products and in vitro diagnostic devices (IVDs; including near-POC tests, true POC tests and self-tests) to be listed in the DxConnect Marketplace.
2. FIND selects diagnostic products for listing in the DxCM through the following methods:
    i. Internal scouting: extraction of relevant data from internal data sources, e.g., the Business Intelligence, Technology & Development or Disease Teams
    ii. Market-based external scouting: searches based on relevant data/insights about market needs or shortcomings

iii. Passive external scouting: submission of data by relevant companies and institutions via an online form

3. The diagnostic tools to be assessed and listed in the DxCM may adhere to the requirements of district, primary or community healthcare levels, i.e., levels of care L2 and L3.

Definitions

Customer support: the range of services to assist customers in getting the most out of a product and resolving any issues. Examples of customer support include answering customer questions, assisting with onboarding, troubleshooting, and upgrading customers to a new product or service.

Due diligence and background checks: FIND's internal process to determine whether a manufacturer (supplier) is eligible to list products in DxCM. The process aims to ensure that, to the extent possible, any benefits in terms of cost savings and quality are passed on to the user, as well as avoiding trade diversion towards non-qualified buyers.

DxConnect Marketplace (DxCM): the DxConnect Marketplace connects buyers and manufacturers of quality assured diagnostics to facilitate procurement through a secure digital platform.

FIND Strategy 2021[1]: FIND's 2021 Strategy aims to accelerate global efforts towards universal health coverage and health emergency responses. It seeks to harness the momentum around testing for COVID-19, exploiting emerging digital innovations and building on the organization's 20-years of experience as a Product Development Partnership focused on the diagnosis of tuberculosis (TB), malaria and fever management, hepatitis C and neglected tropical diseases (NTDs).

Global access: this refers to the requirements in accordance with FIND's Global Access Policy, to which the Parties hereby subscribe as set out under www.Finddx.org to ensure that any product arising from this agreement will be made accessible and affordable to people living in LMICs.

International Medical Device Regulators Forum (IMDRF): a global, voluntary organization of medical device regulators; it works to strengthen the groundwork laid by the Global Harmonization Task Force on Medical Devices (GHTF) and to accelerate the harmonization and convergence of international medical device regulations. Representatives from WHO and from the medical device regulatory agencies of Australia, Brazil, Canada, China, the European Union, Japan, the United States and others gathered in Ottawa in October 2011 to discuss the creation and administration of this new forum[2].

[1] FIND Strategy 2021 - https://www.finddx.org/wp-content/uploads/2021/05/FIND-strategy-2021_FINAL.pdf

[2] About IMDRF https://www.imdrf.org/about

International Organization for Standardization (ISO)[3]: ISO 13485:2016 specifies requirements for a quality management system (QMS) in situations where a manufacturer/organization must demonstrate its ability to consistently provide medical devices and related services that meet customer and applicable regulatory requirements.

Manufacturer (supplier): an entity that is contracted by FIND to supply diagnostic products to buyers.

Medical Device Single Audit Program (MDSAP): MDSAP enables a single regulatory audit of a medical device manufacturer's quality management system to be conducted that satisfies the standards of numerous regulatory jurisdictions. The MDSAP criteria are audited by auditing organizations that have been approved and recognized by the cooperating regulatory authorities to perform audits. Medical device manufacturers can have their compliance with the standards and laws of up to five distinct medical device markets, including Australia, Brazil, Canada, Japan, and the United States, audited once through the MDSAP.[4]

Next-generation diagnostic technology[5]: this refers to the latest diagnostic technology; this may include a new rapid diagnostic tool or an improved conventional technology that provides an accurate and rapid diagnosis, improved accessibility (with or without real-time monitoring of a person's health) and aids in optimizing the patient journey, thereby improving a patient's quality of life. Some game-changing advances in technology have included:

1. Digital solutions employing artificial intelligence and machine learning
2. Technologies leveraging mobile devices and connectivity for increased outreach and to enable real-time monitoring
3. Genomics and CRISPR sequencing technology for disease surveillance and rapid responses
4. Self-monitoring wearables for early detection and ambulatory management
5. Sustainable solutions that minimize the impact on the environment

National Regulatory Authority (NRA): the official, national government body of a country that governs regulatory activities for IVD products within its jurisdiction.

Non-conforming product: any product that does not match the commercial, technical or quality specifications, either in this agreement or in any individual purchase order(s) pursuant to this agreement.

Point-of-care test (POCT): a POCT can be categorized as a true POC test or a near-POC test. True POC tests comprise a portable, battery-operated, enclosed cartridge-based system (one instrument/cartridge with on-board reagents), which has a fully automated sample-to-result process, requires no laboratory

[3] ISO 13485 Medical Devices Quality Management Systems - https://www.iso.org/standard/59752.html

[4] Medical Device Single Audit Program (MDSAP), US Food and Drug Administration. Website: https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

[5] FIND Strategy 2021-2023 Website: https://www.finddx.org/wp-content/uploads/2021/05/FIND-strategy-2021_FINAL.pdf

equipment and can be operated by a non-laboratory health worker. Sample preparation requires addition of reagents/sample using a transfer pipet and the result output is simple (yes/no/invalid), and the system has USB/Bluetooth/wi-fi connectivity. A near-POC test comprises desktop equipment involving an enclosed cartridge-based system, which may have multiple transfer steps or require several instruments. The test requires a mains/electrical supply to function, with the testing process fully automated (separate automated sample preparation is acceptable). The test also requires a calibrated pipet (centrifuge acceptable), which must be performed by a certified laboratory technician (certified for at least 1 to 2 years). The test requires reagent/sample addition with a calibrated pipet (all sample preparation materials should be included in kit), and the results output has a software-based interface.

Post-market recall*:* Removal of a diagnostic product from the market of distribution due to any reported adverse events that occur during the use of the diagnostic product, and which require immediate corrective action to prevent any further harm to patients.[6]

Private health sector: any non-governmental entity that operates on a for-profit basis, but which may have access to preferential access conditions to a product such as set out under the Global Access Policy and as determined by FIND on a case-by-case basis.

Public health sector (PHS): (i) any government in an LMIC, including any government ministry of health, department or agency; or any local or regional governmental body, authority or entity; (ii) international non-governmental organizations such as WHO and UNICEF; (iii) bilateral and multilateral donors such as USAID, PEPFAR, the Global Fund and Unitaid; and (iv) any officially recognized, not-for-profit organizations including private not-for-profit organizations or funds that pursue activities to relieve suffering, promote the interests of the poor, provide basic social services, or undertake community development, including, but not limited to, Save the Children Fund, and Médecins Sans Frontières.

Quality assurance (QA): refers to all actions taken, from the manufacturing process to the selection and use of a diagnostic tool/product, including quality monitoring, to ensure that the diagnostic tools/products are of the requisite quality for the manufacturer's intended utilization of the product/tool.

Quality management system (QMS): A system that directs and controls an organization's quality, for quality system essentials such as facilities and safety, organization, personnel, equipment, purchasing and inventory, process control (quality control, QC), information management, documents and records, customer service, and external quality assessment (EQA).

Self-declared product*:* manufacturers may place diagnostic tests on the market without any explicit permission from authorities once they have declared the compliance of the product with the relevant legislation and affixed the CE marking on the product themselves.

[6] GHTF: Medical Devices Post market Surveillance: Global Guidance for Adverse Event Reporting for medical devices, 30 November 2006. Website: https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n54r8-guidance-adverse-events-061130.pdf

Stringent regulatory authority (SRA) A regulatory authority of one of the founding members of the Global Harmonization Task Force (GHTF), i.e., Australia, Canada, the European Union, Japan or the United States

Target healthcare levels: in this document refer to the focus level of healthcare that is to ensure accurate, accessible and affordable rapid diagnostic tests and Point-of-care (POC) tests, at the basic health care levels in LMICs. These include the district (technician), primary healthcare (healthcare workers) and community (community health workers) levels. Furthermore, the tests are user-friendly, robust, quick, equipment free and applicable to resource limited settings[7]. Considering these levels have limited access to laboratory facility and capacity, testing must be simple to perform and provide quick findings and patients do not have to travel large distances for their results and treatment. These diagnostic tests are low-cost and simple to administer, making them ideal for screening procedures.

Target product profile (TPP): a TPP provides details on the minimum and optimal performance and operational characteristics of priority diagnostic tests. Researchers, developers and manufacturers use TPPs to ensure that R&D activities are focused on relevant products and designed for the contexts and needs of end-users.

Tech scouting: a service performed by consulting companies (in the case of this criteria, by FIND), which consists of searching various sources for technologies potentially beneficial to the company. It includes:

- analysing new scientific research
- identifying emerging technologies in products and processes
- analysing research trends and publications from research institutions
- analysing the adoption of technology by industry
- analysing innovative activities
- identifying complementary technologies

WHO model list of essential in vitro diagnostics (EDL) (third edition): this list acts as an evidence-based reference point for countries to help them in developing their own national lists to guide the choice and usage of IVDs. The EDL recognizes that IVDs are essential for advancing universal health coverage (UHC), addressing health emergencies and promoting healthier populations.[8]

(WHO or SRA) QMS requirements: the current QMS requirements applied and certified by WHO prequalification or by the SRA (as the case may be), which ensure that in vitro diagnostic products are consistently produced and controlled according to quality standards appropriate to their intended use.

WHO prequalification*:* a service provided by WHO to ensure that diagnostics and other medicinal products have been assessed, validated and found to be acceptable for usage and procurement.

[7] Land, K.J., Boeras, D.I., Chen, XS. et al. REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. Nat Microbiol 4, 46–54 (2019). https://doi.org/10.1038/s41564-018-0295-3
[8] The selection and use of essential in vitro diagnostics: report of the third meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2020 (including the third WHO model list of essential in vitro diagnostics). Geneva: World Health Organization; 2021 (WHO Technical Report Series, No. 1031). Licence: CC BY-NC-SA 3.0 IGO.

Section 1 – Criteria overview

1. Each applicant shall abide by the criteria established in this criteria document as well as those policies applicable to all users of DxConnect Marketplace.
2. Product selection and evaluation will only begin once a Supplier has been approved by the due diligence process.
3. The Supplier is only authorized to list the product that has been selected, assessed and has been approved in the selection and quality process established in this criteria.
4. If the product has gone through any changes that alter its characteristics, use or commercialization, FIND and the Buyer(s) must be informed within (five) business days.
    a. If the change is major and alters the use of the product, FIND will remove the product from the catalogue and re-initiate the quality assessment process.
5. In case of any recall, the Supplier must inform FIND and the Buyer within 5 (five) business days.
6. The FIND team will review the data as well as the product dossier provided and evaluate the product against the technical areas listed in the sections laid out in this document.
7. The Supplier will be informed of the quality process undertaken and will be requested to provide written clarification if necessary.
8. Once approved and listed in the DxConnect Marketplace, the diagnostic product is under continuous quality monitoring.
9. Product performance (*applicable to all diagnostic groups in this criteria)*
    a. Product performance is determined by disease category, test type and intended use. These requirements will be publicly available via FIND's website and in the DxConnect Marketplace.
    b. An external panel may review the applicants and indicate which suppliers/diagnostics meet the minimum quality specifications specified in *Technical Areas for Quality Assurance.*
    c. If any changes in the product performance are confirmed, FIND will remove the product from the DxConnect Marketplace and inform the Supplier within 24 hours.
10. FIND will ensure, to the best of its ability, to complete the quality process in a reasonable time.
11. If a product does not been qualify for listing in the DxConnect Marketplace, FIND will not accept any appeals against the decision.
    a. FIND will inform the Supplier of the reason why the product has been disqualified.
    b. If the Supplier wishes to reapply the product for another quality assessment, FIND will only accept the reapplication if the previously missing criteria have been addressed.

Section 2 – Diagnostic product selection criteria (also known as first assessment)

1. For a diagnostic tool to be quality assessed and listed in the DxConnect Marketplace, it must fulfil the following criteria:
   1.1 The diagnostic product must be **within one of FIND's disease** areas, as listed below**:**
      a. Antimicrobial Resistance
      b. Fever and Malaria
      c. Hepatitis
      d. COVID-19
      e. Neglected Tropical Diseases (NTDs)
      f. Non-communicable diseases (NCDs)
      g. Pandemic Threats
      h. Tuberculosis
      i. Women's Health
   1.2 The diagnostic product must focus on one of the following **healthcare levels:**
      a. District (technicians)
      b. Primary (health workers)
      c. Community level (community healthcare workers)
      d. Private sector channels (pharmacy, private clinic, private laboratory networks)
   1.3 The fundamental technology should be **marketplace relevant** in being either a rapid POC testing device (near or true) or a self-testing device.
   1.4 The diagnostic product **must be recommended** as an essential diagnostic tool and listed in the third edition of the WHO model list of essential in vitro diagnostics (WHO EDL), OR it is listed in the national EDL guidelines in the country of commercialization, OR it is a next - generation tool that has been SRA- and/or NRA-approved.

Section 3: Quality assurance process (also known as second assessment)

1. The quality assurance (QA) process is initiated once a product has passed into section 2 and the supplier has been approved in the due diligence process.[9]

[9] The product quality assurance checks are aligned with the tech scouting metrics and methodologies applied at FIND.

2. First, the diagnostic product will be classified into one of the following groups, based on their regulation/authorization assessment:

Group A	**Mature regulated products**	Products that have international authorization (SRAs, WHO) and/or at least two legal national regulatory authorizations from IMDRF members (other than GHTF Founding members) or at least three legal national regulatory authorizations from regional harmonization initiatives (*Refer to Annexure A).*
Group B	**Local manufacturing**	Products that only have one national regulatory authorization (NRA) for manufacturing. These products can only be commercialized in the country of authorization

2.1 Each of the two groups has a specific process in place, as set forth in this document, for the quality assessment of the diagnostic products in that group.

3. Quality assessment is performed across six technical categories (as per Annexure B), according to the group that the product is part of (Group A or Group B).
   i. Design and manufacturing information
   ii. Regulatory description
   iii. Product performance specifications, validations and verification studies
   iv. Labelling of the product
   v. Quality management system
   vi. Customer support in LMICs

Section 3.1: Quality assurance process for Group A

Phase I - Assessment of Regulatory/Authorization Status

1. Applicants must provide a dossier with all required original documentation and information as follows:
   i. Regulatory – international and/or national regulatory registration certificates.
   ii. Performance and technical evaluation studies from FIND or any other national/state reference laboratories.
   iii. Certifications for QMSs; examples of acceptable regulatory standards include the ISO 13485:2016 (medical devices), the US FDA Quality System Regulations (Code of Federal Regulations Title 21, Part 820) and the MDSAP core audits (Australia, Canada, Brazil, USA and Japan).
   iv. Product labelling and packaging information – high quality outer labels and packaging pictures visible from all sides with clearly legible text and other details.
   v. Product instructions for use (IFUs) and other relevant materials.

vi. Except for products that are WHO Prequalified or WHO Emergency Use Listed (EUL), the manufacturer must provide SOPs for post-market surveillance. These SOPs will also include processes in place for, at a minimum, handling customer complaints, vigilance reporting, procedures for recalls, and corrective and preventive action to be taken.

2. Once all the documentation set out in the previous paragraph has been received by FIND, the quality assessment will verify if:

i. The diagnostic product is WHO Prequalified (WHO PQ). If yes, the product is then approved for the *Phase II - Technical Characteristics Assessment for Group A products.*

ii. If rule (i) is not applicable, the diagnostic product must not be a 'self-declared' product and must have been authorized by at least, one of the SRA/GHTF founding members (as per Annexure A). If this condition is fulfilled, the product is then approved for *Phase II - Technical Characteristics Assessment for Group A products.*

iii. If rule (ii) is not applicable, and the diagnostic product is self-declared, it must be registered with at least two GHTF founding members (as per Annexure A). If yes, the product is then approved for *Phase II - Technical Characteristics Assessment for Group A products.*

iv. If rule (iii) is not applicable, the diagnostic product must be registered with at least two IMDRF member states other than the GHTF founding members (as per Annexure A), namely, China, Brazil, Russia, Saudi Arabia, Singapore and South Korea. If yes, the product is then approved for *Phase II - Technical Characteristics Assessment for Group A products.*

v. If rule (iv) is not applicable, then the diagnostic product should be registered with at least three countries from one of the Regional Harmonization Initiatives (list of countries in Annexure A) below:

   a. PAHO countries
   b. Global Harmonization Working Party (GHWP)
   c. APEC LSIF Regulatory Harmonization Steering Committee

   Upon verification of the documents as per rule (v), if the diagnostic product is compliant, then it is approved for *Phase II Technical Characteristics Assessment for Group A products.*

vi. If rules (iv) and (v) are not applicable and the product is registered with just one country, then the product must be assessed as per the technical characteristics in Group B (local manufacturing).

Phase II – Technical characteristics assessment for Group A products

Diagnostic products in Group A will be assessed as per the technical criteria outlined below:

1. **Assessment of product performance:** the product performance will be assessed based on independent performance evaluations (WHO/FIND/state or national reference laboratories); the performance must be within the minimum/optimal WHO TPP guidelines or within FIND's recommendations.
2. **Post-market surveillance:** the product must not have been subject to any major post-market recalls or rejections from application processes with a regulatory agency.
   i. Post-market surveillance will not be assessed if a product is WHO Prequalified or WHO EUL listed.

3. **Labelling:** the labelling of the product shall meet the requirements of WHO Technical Guidance Series 5 (WHO TGS 5)[10] or ISO standards 18113 – In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling)[11]
   i. Assessment of labelling is not required if the product is WHO Pre-qualified or WHO EUL listed.

4. **Quality management system:** there will be an assessment of the QMS certification provided by the manufacturer. The Supplier must present certification from either of the internationally accredited QMS assessments.
   i. Acceptable QMS assessments are:
      - ISO 13485: Medical Devices[3]
      - MDSAP Core Audit – Australia, Brazil, Canada, Japan and USA[4]
      - Code of Federal Regulations part 820 (FDA)[12]

5. **Post-market support in countries of distribution:** A supplier's SOPs shall comply with clauses s8.2.2, 8.2.3, 8.3.2, 8.3.3 of the ISO standard 13485[3]
   i. Post-market support is not to be assessed if a product is WHO Pre-qualified or WHO EUL listed.

[10] WHO Technical Guidance Series – Designing instructions for use for IVDs TGS 5
https://extranet.who.int/pqweb/sites/default/files/documents/WHO_PQT-TGS5-201705.pdf
[11] ISO 18113 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) https://www.iso.org/standard/79866.html
[12] US FDA - Code of Federal Regulations Title 21 ://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820

Section 3.2: Quality assurance process for Group B (locally manufactured products)

Phase I - Assessment of regulatory/authorization status

1. Applicants must provide a dossier with all required original documentation and information as follows:
    i. Regulatory – national regulatory registration certificates
    ii. Performance and technical evaluation studies from FIND or any other national/state reference laboratories
    iii. Certifications for QMSs – examples of acceptable regulatory standards include ISO 13485:2016 (clinical use devices), ISO 9001 certificates (non-clinical use devices), the US FDA Quality System Regulations (Code of Federal Regulations Title 21, Part 820) and the MDSAP core audits (Australia, Brazil, Canada, Japan and USA)
    iv. Product labelling and packaging information – high quality outer labels and packaging pictures visible from all sides with clearly legible text and other details
    v. Product IFUs and other relevant materials
    vi. The manufacturer must provide SOPs for customer support in the region of registration and commercialization. These SOPs will include processes in place for, at a minimum, customer complaint handling in the proposed countries of distribution. These SOPs will be assessed against the ISO clauses 13485 s8.2.2, 8.2.3, 8.3.2 and 8.3.3[3]
2. Once all the documentation set out in the previous paragraph has been received by FIND, the quality assessment will verify if:
    i. The diagnostic product is registered with any National Regulatory Authority. If yes, the product is then approved for *Phase II - Technical Characteristics Assessment for Group B products*
    ii. In any cases where a diagnostic product is not registered with any national regulatory authority, no further assessments will be made, and the manufacturer shall be notified to provide necessary documentation as per this criteria

Phase II – Technical characteristics assessment of Group B products

A diagnostic product will be assessed as per the technical criteria below:

1. **Assessment of product performance:** the product performance will be assessed based on independent performance evaluations (WHO/FIND/state or national reference laboratories); it shall also be within the minimum/optimal WHO TPP guidelines or within FIND's recommendations.

2. **Post-market surveillance:** the product must not have been subject to any major post-market recalls or rejections from an application process with a regulatory agency.

3. Quality management system

i. If the product is for clinical use, then it will be assessed against ISO 13485 certificate[3]
ii. If the product is for non-clinical use, then it will be assessed against ISO 9001 certificate[13]

4. Labelling: if the product is for clinical use, the labelling of the product shall conform to either the requirements of WHO Technical Guidance Series 5 (WHO TGS 5)[10] or ISO standard 18113: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling)[11]

5. Customer Support: the supplier SOPs related to complaint handling and post-market support in the proposed countries of distribution shall be assessed against clauses s8.2.2, 8.2.3, 8.3.2, 8.3.3 in the ISO standards 13485.[3]

Section 3.3: Quality assurance process for other types of products

1. Diagnostic products with Emergency Use Authorization

Diagnostic products which have Emergency Use Authorization (EUA) from any GHTF founding member or are WHO EUL will have an expedited quality approval process, facilitating the availability and accessibility of these products during public health emergencies.

2. Diagnostic products for research-use only or epidemiological mapping and surveillance tools

i. Applicants must provide a dossier with all required original documentation and information as follows:

   a. Regulatory registration certificates (if registered with any national/international regulatory authority)
   b. Independent performance and technical evaluation studies from FIND or any other national/state reference laboratories
   c. Certifications for QMSs – acceptable regulatory standards include the ISO 13485 (clinical use devices) or ISO 9001 certificates (non-clinical use devices)
   d. Product labelling and packaging information – high-quality outer labels and packaging pictures visible from all sides with clearly legible text and other details.
   e. Product IFUs and other relevant materials

[13] ISO 9001 Certificate - https://www.iso.org/standard/62085.html

f. Applicants must provide comprehensive SOPs related to complaint handling, to ensure post-market support in the proposed countries of distribution

ii. These products will be assessed against the following rules:

a) **Assessment of authorization status** – a product should be registered with at least one national/international regulatory authority.

b) **Quality Management Systems Assessment**

a. If the product is for clinical use, it must have an ISO 13485 certificate[3]

b. If the product is for non-clinical use, it must have an ISO 13485[3] or an ISO 9001 certificate[13]

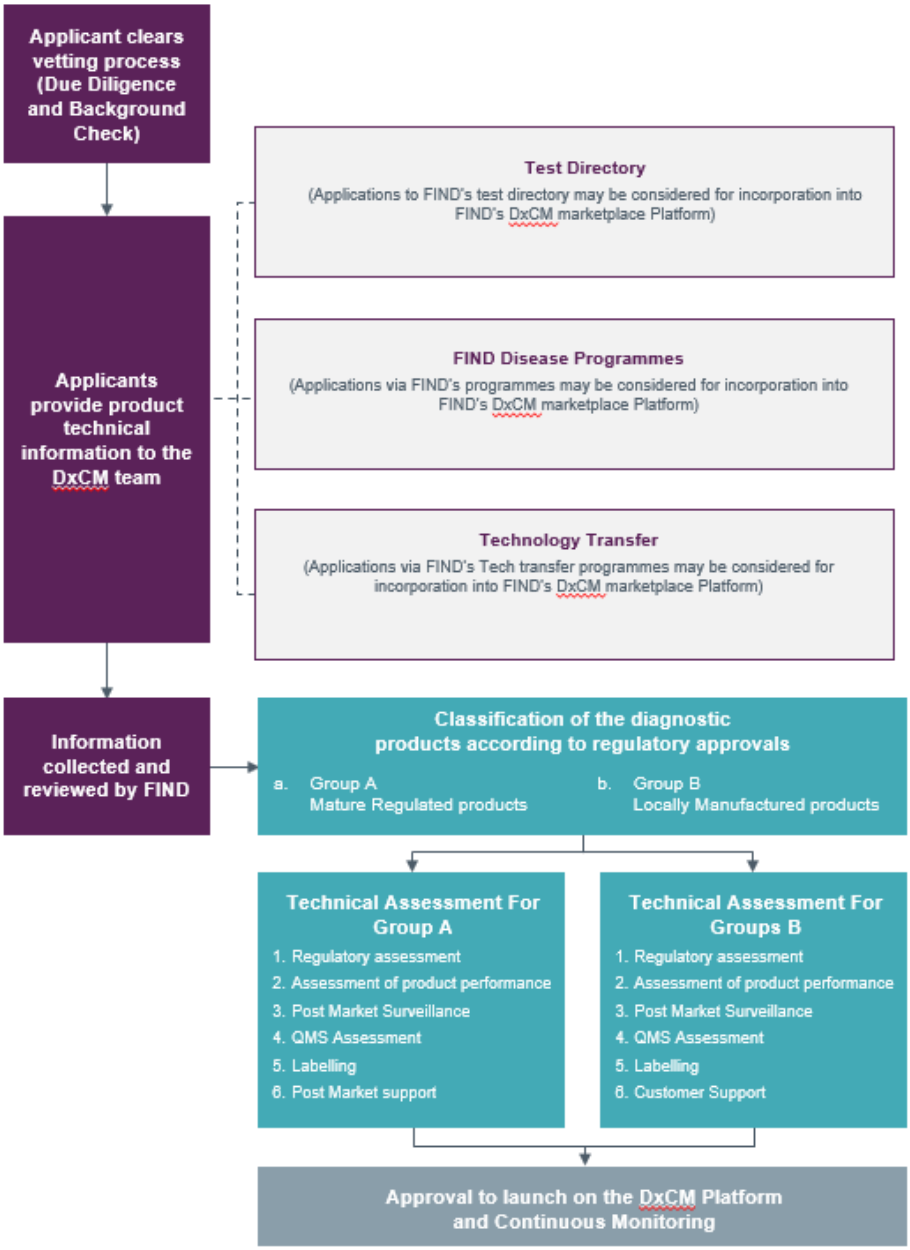
c) **Labelling**

a. If the product is for clinical use, it must comply with WHO Technical Guidance Series 5 (WHO TGS 5)[10] or the ISO standard 18113: Labelling requirements for IVD Medical Devices[11]

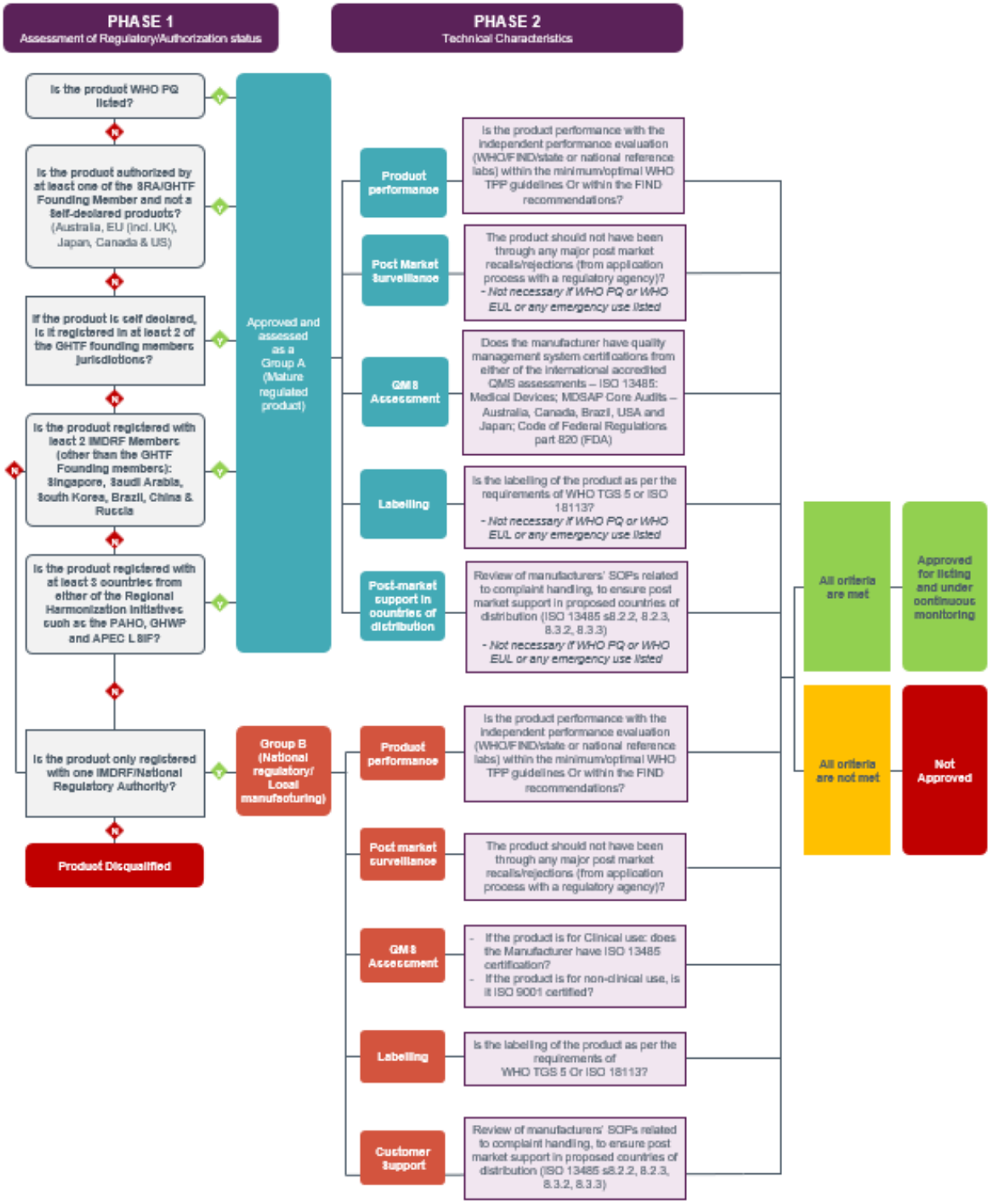
b. If it is an unregulated product, the product must comply with ISO standard 18113[11]

d) **Customer Support**: SOPs must comply with clauses s8.2.2, 8.2.3, 8.3.2,8.3.3 in the ISO standards 13485[3]

Section 4 Summary – QA process for listing a product on the DxConnect Marketplace



Section 5 – Detailed decision tree: QA process for listing a product on the DxConnect Marketplace



Annexure A

IMDRF – International Medical Device Regulators Forum[2]

GHTF Founding Members	Australia, EU including UK, Japan, Canada and USA
IMDRF members (apart from GHTF founding members)	Singapore, Saudi Arabia, South Korea, Brazil, China and Russia
Official Observers	WHO and Argentina
GHWP/Asian Harmonization working Party	Brunei, Cambodia, Chile, Taiwan, Hong Kong, India, Indonesia, Jordan, Kazakhstan, Bahrain, Kyrgyz Republic, Laos, Malaysia, Mongolia, Myanmar, Pakistan, the Philippines, Kenya, Korea, Singapore, South Africa, Kuwait, Oman, Tanzania, Thailand, UAE, Viet Nam, Yemen, Zimbabwe
Pan American Health Organization (PAHO)	MEMBERS: Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Lucia, St. Vincent and the Grenadines, St. Kitts and Nevis, Suriname, Trinidad and Tobago, USA, Uruguay, Venezuela. ASSOCIATE MEMBERS: Aruba, Curaçao, Puerto Rico, Sint Maarten
APEC LSIF Regulatory Harmonization Steering Committee	USA, Canada, Mexico, Peru, Chile, Republic of Korea, Japan, Taipei, Hong Kong, the Philippines, Brunei Darussalam, Papua New Guinea, Indonesia, Australia, New Zealand, Singapore, Malaysia, Thailand, Viet Nam, China, Russia

Annexure B

Summary of technical requirements for listing a product on the DxConnect Marketplace

Technical Area	Criteria
Design and manufacturing information	- Location where the product is designed and manufactured - Lead contact and submitter details - Type of institution/company/manufacturer - Collaborating institutions/funders
Regulatory description	- Relevant international standards – WHO Prequalification/SRA/NRA - Additional national regulatory standards recognized pertaining to the target country of distribution - Flexibility to apply for registration despite the size of the market - Licence expiration dates/validity requirements for all registrations is mandatory
Product performance specifications, validations and verification studies	*Information on the relevant minimum/optimal TPP requirements* - *Product/technology* - product/technology name; stage of development; disease area; technology area; disease area sub-type; other disease applications; type of technology assay target; validated sample types; primary use case; self-testing/self-collection; multiplexing capacity; level of multiplexing - *Performance validations* - clear details of company-sponsored/independent evaluations; clinical sensitivity; clinical specificity; study design; number of positive/negative samples - *Platform/operations* - laboratory versus POC; level of automation; throughput; end-user profile; instrument requirements; type of instrument; operating conditions; connectivity options; data format; companion solutions/reagents required
Labelling of the product	- Established and proprietary names of the product in clear and legible format

	- The language of the labelling must be in English unless otherwise indicated to be in the target country's local language - Details to be included: product reference/catalogue number; kit contents; number of tests per kit; shelf-life; storage conditions; number of manufacturing sites; manufacturing capacity; price of instrument; price of test; distribution; network in LMICs; products sold in LMICs
Quality management system	- At a minimum, ISO 13485-recognized QMS system
Customer support in LMICs	- Customer access: how can a customer avail themselves of customer care services? - Customer service availability: what is the timing to obtain this service? - Type of interaction: what is the nature of the dialogue – telephone/web online form/ email/other - Potential problems: are there any problems a customer might face in accessing the support? - Scalability: can the support be scaled up to handle additional customers?

Note: The information in the table is universal and applicable to all diagnostic products. However, any of the technical areas could be expanded depending on the product.