January 16, 2026

Qure.ai Technologies
℅ Sri Anusha Matta
Director- Regulatory and Clinical Affairs
6th Floor, Wing E, Times Square, Andheri- Kurla Road, Marol
Andheri (East)
MUMBAI, MAHARASHTRA 400059
INDIA

Re: K251934
Trade/Device Name: qXR-Detect
Regulation Number: 21 CFR 892.2070
Regulation Name: Medical Image Analyzer
Regulatory Class: Class II
Product Code: MYN
Dated: June 24, 2025
Received: December 8, 2025

Dear Sri Anusha Matta:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251934

Device Name
qXR-Detect

Indications for Use *(Describe)*
qXR-Detect is a computer-assisted detection (CADe) software device that analyzes chest radiographs and highlights suspicious regions of interest (ROIs). The device is intended to identify, highlight, and categorize suspicious regions of interest (ROI). Any suspicious ROI is highlighted by qXR-Detect and categorized into one of six categories (lung, pleura, bone, Mediastinum & Hila & Heart, hardware and other). The device is intended for use as a concurrent reading aid. qXR-Detect is indicated for adults only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

qXR-Detect

1 SUBMITTER

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Primary Contact Person: Sri Anusha Matta, Director of Regulatory and Clinical affairs.
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Date Prepared:

2 SUBJECT DEVICE

Name of Device:	qXR-Detect
Classification Name:	Medical image Analyzer
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2070
Product Code:	MYN

3 PREDICATE DEVICES

Name of Device:	Chest CAD
Manufacturer:	Imagen Technologies, Inc
510(k) Number:	K210666
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.2070
Product Code	MYN

4 INTENDED USE / INDICATIONS FOR USE:

qXR-Detect is a computer-assisted detection (CADe) software device that analyzes chest radiographs and highlights suspicious regions of interest (ROIs). The device is intended to identify, highlight and categorize suspicious regions of interest (ROI). Any suspicious ROI is highlighted by qXR-Detect and categorized into one of six categories (lung, pleura, bone, Mediastinum & Hila & Heart, hardware and other). The device is intended for use as a concurrent reading aid. qXR-Detect is indicated for adults only.

5 DEVICE DESCRIPTION

qXR-Detect is a computer-assisted detection (CADe) software device that analyzes chest radiographs and highlights suspicious regions of interest (ROIs). The device is intended to identify, highlight and categorize suspicious regions of interest (ROI). Any suspicious ROI is highlighted by qXR-Detect and categorized into one of six categories (lung, pleura, bone, Mediastinum &Hila & Heart, hardware and other). qXR-Detect is indicated for adults only. qXR-Detect is an adjunct tool

and is not intended to replace a clinician's review of the radiograph or his/her clinical judgment. The users must not use the qXR-Detect generated output as the primary interpretation.

The qXR-Detect device is intended to generate a secondary digital radiographic image that facilitates the confirmation of the presence of suspicious region of interest within the categories on a chest X-Ray. This device is intended to be used by trained professionals- ER physicians, family medicine practitioners, and radiologists.

The software works with DICOM chest X-ray images and can be deployed on a secure cloud server. De-identified chest X-rays are sent to qXR-Detect via HTTPS from the client's software. Results are fetched by the client's software and then forwarded to their PACS or any other systems including but not limited to specified radiology software database once the processing is complete or to the console of the digital radiographic processing system.

The underlying algorithm was trained on the large data set of ~2.5 million Chest X-Ray scans which consisted of scans from the US, EU, India, Vietnam, Brazil. These scans consisted of various abnormal regions of interest.

6 COMPARISON WITH PREDICATE DEVICE

Table 1 Comparison between qXR-Detect and the Predicate Device

Components and Characteristics	**Subject Device**	**Predicate Device**
Regulation Information		
Device Name	qXR-Detect	Chest-CAD
Manufacturer	Qure.ai Technologies Pvt. Ltd.	Imagen Technologies, Inc.
510(k) Number	-	K210666
Regulation Number/Name	21 CFR 892.2070 / Medical Image Analyzer	21 CFR 892.2070 / Medical Image Analyzer
Product Code	MYN	MYN
Intended Use	qXR-Detect is a computer-assisted detection (CADe) software device that analyzes chest radiographs and highlights suspicious regions of interest (ROIs). The device is intended to identify, highlight and categorize suspicious regions of interest (ROI). Any suspicious ROI is highlighted by qXR-Detect and categorized into one of six categories (lung, pleura, bone, Mediastinum & Hila & Heart, hardware and other). The device is intended for use as a concurrent reading aid. qXR-Detect is indicated for adults only.	Chest-CAD is a computer-assisted detection (CADe) software device that analyses chest radiograph studies using machine learning techniques to identify, categorize, and highlight suspicious regions of interest (ROI). Any suspicious ROI identified by Chest-CAD is assigned to one of the following categories: Cardiac, Mediastinum/Hila, Lungs, Pleura, Bone, Hardware, or Other. The device is intended for use as a concurrent reading aid for physicians. Chest-CAD is indicated for adults only.
Patient Population	Adults with Chest Radiographs	Adults with Chest Radiographs
Indications for Use		

Image Modality	Chest Radiographs	Chest Radiographs
Clinical Finding and Clinical Output	Suspicious regions of interest (ROI) To inform the primary diagnostic and patient management decisions that are made by the clinical user.	Suspicious regions of interest (ROI) To inform the primary diagnostic and patient management decisions that are made by the clinical user.
Intended Users	ER physicians, Family medicine practitioners and radiologists	Physicians
Software and Technical Information		
Machine Learning Methodology	Deep Learning	Deep Learning
Image Source	DICOM Source (e.g., imaging device, intermediate DICOM node, PACS system, etc.)	DICOM Source (e.g., imaging device, intermediate DICOM node, PACS system, etc.)
Image Viewing	PACS system Image annotations made on copy of original image.	PACS system Image annotations made on copy of original image or image annotations toggled on/off
Deployment Platform	Deployment on-premises or on cloud and connection to several computing platforms and X-ray imaging platforms such as X-ray radiographic systems, or PACS	Deployment on-premises or on cloud and connection to several computing platforms and X-ray imaging platforms such as X-ray radiographic systems, or PACS
Privacy	HIPAA Compliant	HIPAA Compliant

7 TESTING

Software:
Software verification and validation testing was executed, and documentation was provided as recommended by FDA's Guidance for the Content of Premarket Submission for Device Software Functions (June 2023). During all verification and validation tests carried out for the qXR-Detect software, which included evaluating both the algorithmic functionality and the overall performance of the software and its components, qXR-Detect functioned as designed and successfully met the anticipated performance criteria.
Verification, validation, and testing activities were conducted to establish the performance, functionality, and reliability characteristics of the device. Unit Test, Integration Test, Regression Test and User Acceptance test were carried out to account towards the device's performance non-clinically. Functional testing is done to assess functional requirements of the product. The device passed all the tests based on determined acceptance criteria. Standards Regulatory references Used are ISO 13485: 2016 and IEC 62304:2006+A1:2015.

Non-Clinical Performance Testing:

Nonclinical performance was conducted as a standalone study to assess the device's performance against the ground truth. Most of the scans for the study were obtained from across the US spanning 40 states and 5 regions in the US. The dataset was also well-balanced in terms of gender, with approximately a 50-50 male-to-female distribution. Age distribution spans a wide range, from 22 years to over 85 years.

The ground truth was established by 3 ground truthers annotated the chest X-ray scans for the presence of suspicious ROI categories. If there is at least one ground truth boundary for a particular category, the scan is considered to be positive for that category. A particular scan can be positive for multiple categories.

On comparison with the qXR-Detect output the device perform satisfactorily. The result of the performance is summaries in the table 2.

Table 2 Standalone Performance Testing Results for qXR-Detect

Standalone Performance metrics

Category	AUC (95%CI)
Lung	0.893 (0.879-0.907)
Pleura	0.95 (0.94-0.96)
Mediastinum /Hila	0.891 (0.875-0.907)
Bone	0.879 (0.854-0.905)

Hardware	0.958 (0.95-0.966)
Other	0.915 (0.895-0.935)

Additionally, localization accuracy was also estimated as secondary analyses.

Table 3 Standalone Performance Testing Results for localization - qXR-Detect

Category	wAFROC (95% CI)
Lung	0.831 (0.816-0.846)
Pleura	0.89 (0.875-0.905)
Mediastinum & Hila & Heart	0.867 (0.85-0.883)
Bone	0.821 (0.789-0.852)
Hardware	0.771 (0.759-0.782)
Others	0.871 (0.845-0.897)
Aggregate	0.839 (0.824-0.854)

It was observed that wAFROC was above 0.8 for most categories. This indicates that qXR-Detect is able to demonstrate a good performance in detecting and localizing ROI within the categories.

Clinical Performance Testing:

A clinical performance study was conducted via a multireader multicase study conducted on 301 samples with 18 readers. The readers were radiologists, ER physicians and Family medicine practitioners. The study was designed as fully-crossed concurrent. This study protocol was designed in accordance with FDA's guidance document for industry and FDA staff titled "Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data in Premarket Notification (510(k)) Submissions".

The primary metric of the study was to determine the improvement in readers' detection and localization performance in identifying scans with suspicious chest ROIs in the 6 categories. The same was estimated using a wAFROC metric. The readers read scans in 2 sessions, with a washout period of 28 days between the 2 sessions. The scans were randomized in blocks such scans in one block were read aided and the next unaided in the first session. Scans that were initially read as aided; were read as unaided scans in the second session (after a minimum of 28 days of washout).

To compare reader performance across unaided and aided sessions, the area under the weighted alternative free-response receiver operating characteristic curve (wAFROC-FOM) was employed as the figure of merit for the primary analysis.

The overall wAFROC significantly improved from 0.6894 (0.6453 – 07335) in the unaided reads to 0.7505 (0.7029 – 0.8291) in reads aided by qXR-Detect with an improvement of 0.0611 (0.0320-0.0901) with a significant P value (< 0.001). The wAFROC improved in all categories. The number of false positives per image was also presented. There was an improved in the aided reads, where the number of false positives per image reduced from 0.4182 (0.4012 – 0.4358) in the reads unaided – to

0.3300 (0.3149 – 0.3457) in the reads aided by qXR-Detect. This indicates that the use of qXR-Detect does not cause the users to overcall conditions.

Table 4 wAFROC of reads unaided and aided by qXR-Detect

ROI	wAFROC with 95% CI - Unaided	wAFROC with 95% CI - Aided
Overall	0.6894 (0.6453 -0.7335)	0.7505 (0.7029-0.7980)
Lung	0.7270 (0.6857-0.7682)	0.7908 (0.7525-0.8291)
Pleura	0.7829 (0.7427-0.8230)	0.8460 (0.8127-0.8794)
Mediastinum, Hila and Heart	0.6857 (0.6364-0.7350)	0.7773 (0.7298-0.8248)
Bone	0.7117 (0.6712-0.7522)	0.8133 (0.7745-0.8521)
Hardware	0.7232 (0.6930-0.7533)	0.7330 (0.7044-0.7616)
Other	0.7975 (0.7512-0.8437)	0.8329 (0.7929-0.8728)

17/18 readers showed improvements in wAFROC-FOM in reads aided by qXR-Detect across all categories. All 18 readers demonstrated improvement in detecting and localizing suspicious lung ROIs.

The accuracy of readers in detecting suspicious ROIs on chest X-rays was evaluated using the area under the curve (AUC). The AUC of the ROC curves were estimated and there was a significant improvement in the aided reads, as compared to the unaided reads. The overall AUC for aided reads was 0.8466 (0.8106 – 0.8826) whereas the aided reads showed AUC of 0.8720 (0.8339 – 0.9100). There was improvement observed across all categories.

Table 5 AUROC, Sensitivity and Specificity of reads unaided and aided by qXR-Detect

AUROC 95% CI - Unaided	AUROC with 95% CI - Aided	Sensitivity 95% CI - Unaided	Sensitivity with 95% CI - Aided	Specificity 95% CI - Unaided	Specificity with 95% CI - Aided
0.8466 (0.8106-0.8826)	0.8720 (0.8339-0.9100)	0.8896 (0.8596-0.9195)	0.9338 (0.9096-0.9579)	0.5556 (0.4297-0.6814)	0.6219 (0.5065-0.7373)

We believe that the performance metrics indicate that the device is substantially equivalent to the predicate.

8 PREDETERMINED CHANGE CONTROL PLAN

The qXR-Detect submission contains a Predetermined Change Control Plan (PCCP). Modifications to the algorithm of qXR-Detect will be made in accordance with the guidelines outlines in the "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions". The PCCP describes the modifications that can occur in a controlled manner ensuring the continued safety, effectiveness and performance of the device.

The algorithm modifications will not include any adaptive algorithms that get continuously learn from the environment. There are two modifications outlined in the PCCP, and accordingly, any change will only occur after training, testing and validating the algorithm after which the change will be locked. When the modification is locked this will be communicated to all users through updated labelling via the Instructions for use. Verification and Validation activities will be conducted in accordance with the PCCP to compare the performance of the modified qXR-Detect algorithms to the original model to ensure the safety and effectiveness. The modification details are summarised as follows,

Table 6 Details of Modification M1 and M2

Modifications Summary	
M1 – Data Driven Retraining	
Description	Modification 1 (M1) will involve retraining the existing model using newly acquired, high-quality adult chest radiograph datasets to improve device performance without altering the underlying model architecture.
Rationale	Improve the algorithm performance
Retraining Triggers	The availability of a new, high-quality dataset obtained from different parts of US, that improves the diversity of the training data, offering a logical pathway to improve overall model performance.
Testing Methods	Retraining with newly acquired, high-quality adult chest radiograph datasets, followed by locked test-set evaluation and comparison to baseline model using predefined acceptance criteria. Performance evaluation for Modification 1 will ensure that the retrained CNN-based model continues to operate safely, effectively, and within the boundaries of the device's cleared indications for use. The updated model will be evaluated using a predefined set of clinically meaningful and statistically robust metrics to confirm that the performance is improved without introducing any regression across the six existing condition categories.
Update Procedures/Implementation	Before deployment, each update is reviewed to ensure it stays within the scope of the PCCP with no new outputs, indications, or workflow changes and is released only after all verification and validation confirm it meets predefined success criteria. If these criteria are

	met, the update is implemented through a controlled, manual deployment process and made globally available to all end users. Users will be notified of updates implemented under the PCCP through formal communication channels, including revised labelling, updated user manuals, and detailed release notes. These materials will clearly outline any changes to the device's performance, functionality, or indications for use, and will be disseminated in accordance with established quality system procedures to ensure timely, accurate, and comprehensive stakeholder awareness.
Impact Assessment	**Benefits:** Improved detection and localization performance across six clinically relevant categories; **Risks:** Potential overfitting and unintended bias if new data are imbalanced; risk of minor performance variability. **Risk Mitigation:** The modified model will be tested for non-inferiority on the performance study test dataset which will contain new unseen data.
M2 – Architectural modification	
Description	Modification 2 (M2) will involve a controlled architectural change through modular replacement of the existing Convolutional Neural Network (CNN) encoder with a Vision Transformer (ViT)-based encoder, while maintaining the remaining components and the workflow of the model pipeline.
Rationale	Enhance feature extraction and global context understanding to further improve diagnostic performance
Retraining Triggers	Given the established potential of ViT models, Modification 2 will be explored if a superior Vision encoder becomes available. If the updated architecture demonstrates improvement as described in the Acceptance Criteria, the modification will be accepted.
Testing Methods	For testing the M2 modification, candidate models (trained on ViT architecture) will undergo rigorous evaluation against the baseline CNN model. The updated model will be evaluated using a predefined set of clinically meaningful and statistically robust metrics to confirm that the performance is improved without introducing any regression across the six existing condition categories. Testing

	includes assessment of performance metrics-(AUC, Box level sensitivity, specificity, subgroup analysis). This ensures that candidate model continues to operate safely, effectively, and within the boundaries of the device's cleared indications for use.
Update Procedures/Implementation	Before deployment, each update is reviewed to ensure it stays within the scope of the PCCP with no new outputs, indications, or workflow changes and is released only after all predefined verification and validation confirm it meets predefined success criteria. If these criteria are met, the update is implemented through a controlled, manual deployment process and made globally available to all end users. Users will be notified of updates implemented under the PCCP through formal communication channels, including revised labelling, updated user manuals, and detailed release notes. These materials will clearly outline any changes to the device's performance, functionality, or indications for use, and will be disseminated in accordance with established quality system procedures to ensure timely, accurate, and comprehensive stakeholder awareness.
Impact Assessment	**Benefits:** Improved ROI classification accuracy and localization precision **Risks:** Possibility of new failure modes due to architectural change and model instability; risk of decoder-compatibility errors. **Risk Mitigation:** Full integration verification; performance comparison to baseline using identical metrics and datasets

9 CONCLUSION

The comparison in Table 1 as well as the software & performance testing presented above demonstrate that the qXR-Detect device is substantially equivalent to the predicate device. Both devices are computer-assisted detection (CADe) software devices that analyze chest radiographs using machine learning techniques to identify and localise suspicious regions of interest (ROI). The new device does not introduce fundamentally new scientific technology, and the clinical tests demonstrate that the device is safe and effective.

The qXR-Detect is a software device with similar indications, technological characteristics, and principles of operation as the predicate devices. The comparison of intended purpose, technological

characteristics and performance demonstrates that the qXR-Detect device performs as intended and can be considered as substantially equivalent to the predicate device, Chest CAD (K210666).

Based on the information provided in this premarket notification, including the indications for use, technological characteristics, and performance testing, qXR-Detect is determined to be substantially equivalent to the predicate device. The device does not raise new questions of safety or effectiveness and demonstrates comparable safety, efficacy, and performance.