COMMONWEALTH of VIRGINIA

Department of Health

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December 8th 2025

MEMORANDUM

TO: The Honorable L. Louise Lucas
Chair, Senate Finance Committee

The Honorable Luke E. Torian
Chair, House Appropriations Committee

The Honorable Mark D. Sickles
Vice Chair, House Appropriations Committee

FROM: Karen Shelton, MD
State Health Commissioner, Virginia Department of Health

SUBJECT: Northern Virginia Firefighter Occupational Cancer Screening Pilot Program Interim Report

This report is submitted in compliance with Chapter 2 of the 2024 Virginia Acts of Assembly (Budget Bill), Item 272 (H):

…3. The Virginia Department of Health shall provide an interim report on the pilot program to the Chairs of the House Appropriations Committee and Senate Finance and Appropriations Committee by December 1, 2025 and a report on the evaluation upon completion of the pilot program.

Should you have any questions or need additional information, please feel free to contact me at (804) 864-7002.

KS/KB
Enclosure

Pc: The Honorable Janet Kelly, Secretary of Health and Human Resources

NORTHERN VIRGINIA FIREFIGHTER OCCUPATIONAL CANCER SCREENING PROGRAM

REPORT TO THE HOUSE APPROPRIATIONS COMMITTEE AND SENATE FINANCE AND APPROPRIATIONS COMMITTEE

2025

VIRGINIA DEPARTMENT OF HEALTH

PREFACE

Chapter 2 of the 2024 Virginia Acts of Assembly (Budget Bill), Item 272 (H) directs the Virginia Department of Health to implement the Northern Virginia Firefighter Occupational Cancer Screening Pilot Program through partnership with a health system-affiliated cancer screening center located in Planning District 8. The pilot program is multi-year and requires a randomized clinical trial to investigate the optimal type of full-body imaging for cancer early detection, given the unique occupational cancer risk of firefighters. Through the pilot program, hereafter referred to as "study," at least 450 firefighters must be screened for cancer annually. An independent evaluation of the program will be conducted to assess its effectiveness and its potential for replication by other health systems across Virginia. Budget Item 272 (H) requires VDH to submit an interim report to the Chairs of the House Appropriations Committee and Senate Finance and Appropriations Committee by December 1, 2025 summarizing progress on the pilot program. This report serves to fulfill that requirement.

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EXECUTIVE SUMMARY

The Virginia Department of Health (VDH) is tasked with implementing the Northern Virginia Firefighter Occupational Cancer Screening Pilot Program through a contract with a health system-affiliated cancer screening center located in Planning District 8. As detailed in Chapter 2 of the 2024 Acts of Assembly, the pilot program should be designed to:

1. Be multi-year
2. Screen at least 450 firefighters annually
3. Use an occupational screening and risk assessment for eligible firefighters within a defined age and risk band
4. Conduct a randomized clinical trial investigating the optimal type of full-body imaging for cancer early-detection for the unique occupational cancer risk of firefighters
5. Include an independent evaluation of the pilot program that assesses the effectiveness of the screening program and results of the clinical trials and the potential for use by other health systems in Virginia

Per Chapter 2, VDH is required to provide an interim report to the Chairs of the House Appropriations Committee and Senate Finance and Appropriations Committee on the progress of the pilot program by December 1, 2025. This report serves to fulfill this requirement.

INTERIM FINDINGS

During the period of this report (July 1, 2024 – July 1, 2025), VDH selected and established a contract with Inova Health System, a health system-affiliated cancer screening center located in Planning District 8, to conduct the pilot program. Inova developed the infrastructure for the program and began to implement the program. Details of these activities are included in the report below.

Additionally, although it is early in the implementation of the program, Inova reports the following initial observations and findings:

1. Preliminary observations from the pilot study have demonstrated both a high demand for enrollment in the screening program and the clinical impact of these screenings in the firefighter community.

2. By the end of June 2025, the study had enrolled 195 firefighters, with 195 having completed the Multi-Cancer Detection (MCD) assay, 88 completed whole-body MRI, and 76 completed whole-body ultrasounds. Enrollment could not begin until February 2025 after the IRB was approved.

3. Interest among regional firefighters has exceeded expectations, and as of summer 2025, the study was working from a waitlist of over 400 firefighters.

4. Seven cancers have been diagnosed through the screening program (including 3 skin cancers and 4 solid tumors) among participants that were enrolled through June 2025 and have had their results reviewed (5.3% cancer detection).

5. The clinical team at Inova and the regional firefighter jurisdictions in Planning District 8 have developed and strengthened a strong relationship through regular meetings between the leadership of the departments and through Inova team member ride-alongs and fire station site visits.

6. The Inova team has been recognized for the occupational screening clinic with the Food on the Stove's (a non-profit focused on firefighter health) 2025 Community Health Partner Award, and by regional fire chiefs who presented the clinical research team with a departmental appreciation coin in summer 2025.

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INTRODUCTION

STUDY MANDATE

Effective July 1, 2024, Chapter 2 of the 2024 Virginia Acts of Assembly (Budget Bill), Item 272 (H), required VDH to implement the Northern Virginia Firefighter Occupational Cancer Screening Pilot Program through a contract with a health system-affiliated cancer screening center located in Planning District 8. The pilot program aims to screen at least 450 firefighters annually, establish and use an occupational cancer screening and risk assessment for eligible firefighters within a defined age and risk band, investigate the optimal type of full-body imaging for cancer early-detection for the unique occupational cancer risk of firefighters, and assess the effectiveness of the screening program and its use by other hospitals and health systems in Virginia. The purpose of this report is to provide updates on the progress towards implementing the pilot program to the Chairs of the House Appropriations Committee and Senate Finance and Appropriations Committee.

See Appendix A for the full text of the legislation. The legislation went into effect on July 1, 2024.

STUDY ACTIVITIES

During the period of this report (July 1, 2024 – June 30, 2025), the following activities occurred:

1. VDH selected Inova Health System, a health system-affiliated cancer screening center located in Planning District 8, as the contracted partner to implement this pilot program. VDH and Inova finalized a contract in April 2025.

2. Inova developed a study protocol that outlines the randomized clinical trial to investigate the optimal type of full-body imaging for cancer early detection. Inova's Protocol Review and Monitoring Committee approved the study protocol in September 2024.

3. Inova created a Community Advisory Committee comprised of representation for firefighter jurisdictions in Planning District 8. The purpose of this committee is to provide independent oversight of the trial, including feedback on study design, review of study updates, and troubleshooting concerns as they arise.

4. Following Inova policy, an external institutional review board (IRB) operated by WCG, a national leader in independent review solutions for clinical trials, approved the study protocol in January.

5. Inova selected the vendors providing the whole-body imaging and multi-cancer detection (MCD) assays. Inova finalized the vendor contracts in January 2025.

6. Inova finalized a contract with WCG to establish a Data and Safety Monitoring Board (DSMB) to provide independent oversight of the clinic trial. The board make-up was finalized in July 2025.

7. Enrollment for the pilot program began in February 2025, with the first whole-body imaging screenings taking place during the same month.

8. 195 firefighters were enrolled into the study by the end of June 2025, with 195 completing the MCD assay, 88 completing whole-body MRI, and 76 completing whole-body ultrasound. Inova has increased the planned study enrollment rate in FY26 by adapting workflows and plans to enroll up to 48 firefighters per month moving forward, anticipating to reach the pilot target of 800 firefighters being enrolled and screened with whole-body imaging by July 2026.

Interim observations and findings include the following:

a. Preliminary observations from the pilot study have demonstrated both a high demand for enrollment in the screening program and the clinical impact of these screenings in the firefighter community.

b. By the end of June 2025, the study had enrolled 195 firefighters, with 195 having completed the MCD assay, 88 completed whole-body MRI, and 76 completed whole-body ultrasounds.

c. Interest among regional firefighters has exceeded expectations, and as of summer 2025, the study was working from a waitlist of over 400 firefighters.

d. Seven cancers have been diagnosed through the screening program (including 3 skin cancers and 4 solid tumors) among participants that were enrolled through June 2025 and have had their results reviewed (5.3% cancer detection).

e. The clinical team at Inova and the regional firefighter jurisdictions in Planning District 8 have developed and strengthened a strong relationship through regular meetings between the leadership of the departments and through Inova team member ride-alongs and fire station site visits.

f. The Inova team has been recognized for the occupational screening clinic with the Food on the Stove's (a non-profit focused on firefighter health) 2025 Community Health Partner Award, and by regional fire chiefs who presented the clinical research team with a departmental appreciation coin in summer 2025.

REPORT OUTLINE

This report begins with a brief description of cancer risk among firefighters in Virginia. The report then provides a rationale for and purpose of the pilot program; a breakdown of the study design, recruitment and enrollment practices; a summary of data analysis and evaluation plans; and an update on implementation progress as outlined in Budget Item 272 (H).

CANCER RISK AMONG FIREFIGHTERS

In July 2022, a working group of the International Agency for Research on Cancer (IARC) concluded that occupational work as a firefighter is carcinogenic to humans (Group 1) based on a comprehensive scientific literature review. Many epidemiological studies have evaluated the cancer risks associated with firefighting, including multiple meta-analyses that were considered as part of the IARC Monograph review in 2022 (IARC, 2023; LeMasters, 2006; Casjens, 2020; Jalilian, 2019). These systematic reviews evaluated individual studies that vary in the study design and endpoint (incidence or morality), exposure characteristics of the firefighters, and follow-up time, but have been consistent in suggesting increased risks in firefighters for one or more cancer sites (Demers, 2022).

One of the largest cohort studies conducted to date followed nearly 30,000 urban career firefighters in San Francisco, Chicago, and Philadelphia over a more than 60-year period. The study ultimately observed a higher risk of both total cancer mortality and of seven individual cancer sites, with a total 3,843 cancer deaths observed in the cohort (13% of the total cohort) (Pinkerton, 2020). This confirmed an earlier follow-up of the same study population that found a 9% higher risk of cancer incidence and 14% higher risk of cancer mortality compared to the general U.S. population (Daniels, 2015). The meta-analysis conducted to support the IARC review observed statistically significant risks of colon cancer, melanoma, prostate cancer, testicular cancer, thyroid cancer, and non-Hodgkin lymphoma among the firefighter population (DeBono, 2023). The associations with multiple cancer types are highly biologically plausible given that firefighters are exposed to over a dozen chemicals that are individually known or suspected carcinogens, including various combustion products, particulates from fires, diesel exhaust, and benzene (Demers, 2022).

Therefore, this collective epidemiologic evidence indicates the importance of screening and early detection of cancer at multiple sites among firefighters and recognizes that established screening tools are not currently available for all of the cancer sites reportedly associated with firefighting.

PILOT PROGRAM RATIONALE AND PURPOSE

The classification of firefighting as a Group 1 carcinogen by the IARC has prompted firefighters across the nation to seek out various cancer screening tests that have traditionally not been used or recommended as cancer screening tools for the asymptomatic general population in clinical practice. This includes MCD assays (blood tests to detect multiple types of cancer) and full-body imaging modalities such as magnetic resonance imaging (MRI) and ultrasound. The lack of published data on the impact of their use in firefighters, limited identification of risks and benefits, and absence of established guidelines and understanding of the diagnostic follow-up of abnormal and incidental findings prompted by these tools has raised questions regarding the utility of their use for screening.

The medical community has debated the use of whole-body imaging for preventive screening with concerns for safety, the high-degree of false-positive and possibility of detecting incidental

findings, and costs associated with the follow-up healthcare utilization stemming from their use (Kwee, 2019). Anxiety and other psychosocial effects associated with these factors are also of concern. Some studies evaluating anxiety in relation to cancer screening with established modalities suggest that anxiety levels may increase in individuals prior to communication of screening results or following being informed of positive or indeterminate results (Kim, 2022). Despite these concerns, further research is needed to evaluate the clinical impact of using whole-body imaging for screening given the capability of this technology to detect cancers earlier in asymptomatic individuals (Summers, 2021; Zugni, 2020; Lee, 2018).

With the recognition of the need for new screening tools for cancers that do not yet have established screening tests, multiple types of blood tests to detect cancer biomarkers are currently under clinical development to detect multiple cancers from a single blood sample (Rubinstein, 2024). The specific methodologies vary for these MCD tests with respect to the targeted biological components (e.g., cell-free DNA or RNA, circulating tumor DNA, and proteins and metabolites), the types of cancers that are targeted, the ability to identify the cancer signal origin, and the diagnostic performance (Brito-Rocha, 2023). While MCD assays are currently used in firefighter screening programs across the country, there is no published clinical data on the assay in this population nor how it compares with respect to cancer detection and diagnostic follow-up steps from other imaging modalities that firefighters are receiving, such as whole-body imaging procedures.

Given the lack of published research data on the use of these cancer screening modalities in the firefighter population, the purpose of this pilot is to provide preliminary data on the clinical impact of MCD assays, whole-body MRI, and whole-body ultrasound for screening as well as the diagnostic follow-up and healthcare utilization that results from their use. The pilot further aims to evaluate the efficacy in detecting a cancer signal and the degree to which follow-up diagnostic tests are needed between each whole-body imaging modality and a MCD test in participants within the same screening arm. Additionally, this study aims to understand the feasibility of implementing these screening modalities, describe occupational and cancer related exposure characteristics of the study population, and identify the psychosocial effects (i.e., anxiety) associated with the use of these modalities, given their potential for generating false-positive and incidental findings.

Aligning with pilot program goals, the design and preliminary data will serve as a research framework that can be adopted and tested within other health systems in Virginia and nationally in partnership with local firefighting jurisdictions in their catchment area. The ultimate impact of this research is to provide data on firefighter health and safety that will increase understanding of the clinical impact and risks and benefits that these screening modalities have in real-world, clinical practice.

PILOT PROGRAM IMPLEMENTATION

STUDY OVERVIEW

VDH selected the Inova Saville Cancer Screening and Prevention Center as the health system partner to administer the pilot program. This system was selected due to their clinic infrastructure, expertise in cancer, and existing community partnerships with firefighter jurisdictions serving Planning District 8. In April 2024, Inova launched a firefighter occupational cancer screening and risk assessment clinic as a collaboration between Inova Saville Cancer Screening and Prevention Center and Inova's Department of Occupational Health, which has a long history of conducting annual National Fire Protection Association (NFPA) physical exams for regional firefighters. As part of this clinic, regional firefighters who complete their NFPA exams through Occupational Health are referred to Saville for clinical services beyond traditional cancer screenings, including targeted thyroid ultrasound, dermatology screening with Vectra Imaging, risk assessments, and wellness discussions. This multi-disciplinary cancer screening clinic for firefighters is the first of its kind within Planning District 8.

Inova Saville Cancer Screening and Prevention Center has built upon the already existing resources and infrastructure established through the firefighter multi-disciplinary cancer screening clinic to implement the investigational study of full-body imaging for cancer early-detection as directed in Budget Item 272 (H). The study team is comprised of Inova staff experienced in oncology, clinical research, patient navigation, and data management and analysis. The team is led by Principal Investigator, Dr. Rebecca Kaltman, Executive Director of Inova Saville Cancer Screening and Prevention Center, a board-certified oncologist with over 20 years' experience in the field. Study objectives include:

- Objective 1: To provide preliminary pilot data on the clinical impact of each whole-body imaging procedure and a MCD test in identifying pre-malignancies and malignancies in firefighters.
- Objective 2: To evaluate the follow-up diagnostic evaluations and healthcare utilization associated with each whole-body imaging procedure and a MCD test.
- Objective 3: To understand the anxiety of firefighters in each screening arm pre- and post-imaging exam.
- Objective 4: To understand the feasibility of firefighters completing the screening tests, enrolling a diverse population to the pilot study, as well as describing occupational exposure characteristics, clinical characteristics, and cancer related risk factors of the study population.

The implementation of the firefighter occupational cancer screening and risk assessment clinic has allowed Inova to forge strong working relationships with the firefighter jurisdictions serving Planning District 8. These partners helped provide input on the design and logistics of the whole-body imaging study, including a commitment to ensure that the study population enrolled is representative of the participating jurisdictions. Members of local firefighter

jurisdictions also serve as a community advisory committee for the program, helping to troubleshoot any operational issues and mitigate any enrollment barriers.

VDH and Inova staff worked during the summer and fall of 2024 to finalize a workplan and budget for the pilot program that aligned with the directives outlined in Budget Item 272 (H). On April 18, 2025, the Inova and VDH teams finalized their contract. The contracting process was prolonged as the Inova and VDH teams worked to address the need for confidentially regarding proprietary information related to the MCD assay and imaging services to be used during the study, including the unit price of each screening which needed to be shared with VDH as part of the budget and contracting process.

While the contract was being finalized, Inova developed a study protocol and secured protocol approval from Inova's Protocol Review Monitoring Committee (September 2024) and the external Institutional Review Board (IRB) through WCG (January 2025). In addition, Inova finalized contracts with the companies providing the MCD assays and whole-body MRI and ultrasound imaging (January 2025).

STUDY DESIGN

The pilot study aims to enroll 800 firefighters at least 35 years of age with at least 10 cumulative years of service working as a firefighter. Participants are randomized equally to one of the two screening arms: Whole-body MRI (n=400) and Whole-body ultrasound (n=400). All participants (n = 800) are screened with a MCD assay. Following completion of these screening tests, participants receive their results from the clinical research staff at Saville as well as information on follow-up diagnostic testing, as needed. Follow-up diagnostic testing is dictated by the results of the whole-body imaging and MCD assays as reviewed and recommended by a team of medical providers. Any diagnostic testing needs are billed to the participants' insurance. Research participants are contacted one year (± 2 months) after the date of their whole-body imaging to collect data on cancer status and associated confirmatory clinical data (pathology results, etc.).

Participating firefighters are also eligible to receive other clinical services at Saville based on their risk assessment, including mammography, genetic testing, targeted thyroid ultrasound, stool-based testing for colorectal cancer screening, PSA tests, and/or skin cancer screening. Inova covers the costs of these other "non-study" clinical services, with any required diagnostic follow-up billed to the participants' insurance.

Inova uses medical records and self-reported patient intake questionnaires to collect select information on lifestyle (physical activity, tobacco, drug and alcohol use), medical and surgical history (including select laboratory results), family history of cancer, environmental exposure, and cancer screening history upon enrollment into the study. The Firefighter Occupational History questionnaire collects data on participant's firefighter history, which collects details on duration of employment as a firefighter, whether the participant is a volunteer or career firefighter (and length of time), rank within the fire service, and key exposures and exposure reduction processes while employed in the fire service. This information is used to describe the characteristics of the study population included in the analysis.

Additionally, the State-Trait Anxiety Inventory (STAI) is used to assess anxiety. The STAI is a validated anxiety tool that has been used in a variety of research and clinical settings, including studies of cancer screening (Kim, 2022; Sesti, 2000). Participants complete the STAI at three time points during the study: 1) following their randomization to a whole-body imaging procedure, 2) following completion of their imaging procedure, and 3) after review of their imaging results with the Saville clinical team.

STUDY TIMELINE

The anticipated total study duration is approximately 3-3.5 years. This duration includes whole-body imaging and MCD testing of the planned 800 firefighters over 2-years and their 1-year (± 2 months) follow-up. For an individual participant, the expected duration is 1-1.5 years depending on individual scheduling for completing study screenings and diagnostic follow-up, as necessary. All participants will be re-contacted to assess cancer status and collect confirmatory clinical information (i.e. pathology report) from medical records (for those diagnosed with cancer) 1-year (± 2 months) after completion of their whole-body imaging exam.

The complexities in implementing a study of this nature challenged feasibility to screen 450 firefighters during year one as indicated by Budget Item 272 (H). Due to the time needed to develop a study protocol, receive approval by Inova's Protocol Review Monitoring Committee and from an external IRB, enrollment could not begin until February 2025. Given the anticipated early 2025 implementation timeframe and scheduling considerations for the whole-body imaging procedures and follow-up result visits, the study was designed to enroll and screen 800 participants, targeting 240 enrollees by the end of year one in June 2025.

Final follow-up information on study participants will not be collected until July 2027. Allowing time for data analysis and interpretation, VDH and Inova anticipate the final report detailing clinical outcomes and study results by Spring 2028.

See Appendix C for a breakdown of the study timeline.

STUDY ELIGIBILITY, RECRUITMENT, AND ENROLLMENT

Eligibility criteria for study participants include the following criteria:

- Any sex
- At least 35 years of age with at least 10 cumulative years working as a firefighter
- No prior history of any invasive cancer within the previous 5 years (non-melanoma skin cancer and *in situ* carcinoma would still be eligible) and no current diagnostic workup for suspicion of cancer.
- Completion of NFPA physical examination within the past 6 months for active-duty firefighters
- Have not received a whole-body MRI, whole-body ultrasound, or been tested with a MCD within the past 1-year
- For women of childbearing potential, not pregnant and do not plan to become pregnant for the duration of the study
- Ability to understand and willing to sign informed consent
- Health Insurance Portability and Accountability Act (HIPAA) Authorization

Participants are recruited through a collaborative effort between the Inova Saville Cancer Screening and Prevention Center, Inova Department of Occupational Health, and participating firefighter jurisdictions (Prince William County, Fairfax County and City, Arlington County, City of Alexandria, Loudon County, Manassas, and Metropolitan Washington Airport Authority). The Inova Department of Occupational Health has established relationships with regional firefighter jurisdictions and completed an average of 5,700 NFPA physical exams in 2023. The Inova Occupational Health team discusses the study opportunity with eligible firefighters during their annual NFPA physical exams. Recruitment outreach also occurs through the local firefighter jurisdictions, via distribution of study flyers containing information about the study and enrollment.

All study participants complete informed consent prior to any study activities occurring. Participants receive a copy of the e-consent and HIPAA authorization forms before and after this discussion. Upon completion of the consent forms, the clinical research coordinator formally screens the participant to confirm eligibility criteria.

STUDY DATA COLLECTION

Data sources for this study include participant electronic medical records (EMR), research questionnaires specific to the study (anxiety and occupational exposures), and whole-body imaging and MCD test result reports. The research team enters all data into a central electronic study database maintained by the Inova research team. The collected research data includes results from the whole-body imaging procedure and MCD test results, as well as any diagnostic follow-up resulting from these tests and the 1-year follow-up cancer assessment and data from the research anxiety and occupational exposure history questionnaires.

At baseline, the research team uses medical records to gather routinely collected data on cancer risk factors (physical activity, tobacco, drug and alcohol use), medical and surgical history (including medication use and select laboratory results), family history of cancer, environmental exposure, and cancer screening history. This collection includes results from any other cancer screening tests (e.g., PSA, genetic testing, colonoscopy/blood stool test, breast cancer screening, targeted thyroid ultrasound, skin exams) that participants may receive at Inova as part of their broader participation in the firefighter occupational cancer screening and risk assessment clinic or external to Inova.

See Appendix D for a listing of data elements collected as part of the study.

All data and records generated through the study are kept confidential in accordance with Inova's institutional policies and HIPAA policies on participant privacy. The research team only uses collected data and records for the purpose of conducting the study and does not share any identifiable data with anyone outside the authorized research team. The research team stores all electronic information on systems with password protected access, automatic time out for inactivity, and firewall protections.

STUDY DATA ANALYSIS

The research team will analyze study data to evaluate the clinical impact and risks and benefits that MCD assays and whole-body imaging screening (MRI and whole-body) modalities have in real-world, clinical practice. The proportion of confirmed pre-malignancies or malignancies identified by each investigational screening tool at the end of diagnostic resolution and 1-year (± 2 months) follow-up will be calculated. This will include a calculation of the positive predictive value (PPV), sensitivity, specificity, and negative predictive value (NPV) for each investigational screening tool.

Further, the research team will evaluate the need for follow-up diagnostics by calculating the proportion of participants requiring any diagnostic follow-up procedures for each screening modality as well as the proportion of participants with a false-positive cancer result relative to all participants screened for each investigational screening tool. In addition, the team will estimate average costs associated with diagnostic follow-ups using procedure specific CPT codes and their current Medicare fee schedule. Descriptive statistics will be used to summarize costs within each screening arm, and to summarize the total number and type of follow-up diagnostic procedures and medical visits required, and average time to diagnostic resolution for each investigational screening tool.

The STAI score will help analyze anxiety of study participants at three different timepoints within each screening arm (pre-screening, post-screening, and at the time when screening results are reviewed). The mean ± standard deviation STAI score will be summarized at each time point and the change from the baseline (pre-screening) score will be calculated separately with respect to the post-screening score and the score when screening results are reviewed.

Descriptive statistics will help describe the study population. This will include the mean/median of study participants by age, sex, race/ethnicity, type of service (career, volunteer), job title, in addition to occupational and cancer related exposures. To assess the study's ability to enroll a diverse sample these descriptive statistics will compare the demographic characteristics of the study participants to the overall distribution of these characteristics in each jurisdiction depending on data availability. Lastly, data on medical/surgical history (including select laboratory assessments), family history of cancer, and other cancer screening assessments will be summarized (e.g., mean/median, proportion, prevalence) for the study population within each screening arm.

A detailed breakdown of the study outcomes to be analyzed can be found in Appendix E.

INDEPENDENT OVERSIGHT AND EVALUATION OF THE STUDY

Independent bodies, sometimes referred to as Data and Safety Monitoring Boards (DSMBs), regularly handle oversight of clinical trials. These groups are typically comprised of clinicians and biostatisticians (with at least one of the clinicians being an expert in the therapeutic area of study) who monitor clinical trials to ensure participant safety, the validity of the data collected, and provide recommendations regarding the trial's continuation, modifications, or termination. Inova Saville Cancer Screening and Prevention Center has contracted with WCG, an industry

leader in providing independent review solutions for clinical trials, to establish a DSMB to provide independent oversight of the firefighter occupational cancer screening pilot program and associated clinical study. The board make up was finalized in July 2025, with a kickoff meeting planned for September 2025 to review the study protocol and establish methods for the review of study data and progress through the remainder of the study.

In addition to the DSMB, the Community Advisory Committee also provides independent oversight over the study. The committee meets quarterly with the Inova team to review study updates and progress, discuss operational processes for referring firefighters to the study, and address any concerns or barriers that may arise. There are plans to extend the committee to include representation from the Virginia Department of Fire Programs and/or other Virginia health systems to help address the applicability of the study to be replicated in other communities in the Commonwealth. Inova will share final study outcomes with the committee, and their recommendations for replication by other health systems will be included as part of the overall evaluation of the pilot program.

STUDY PROGRESS TO DATE

Before implementation of any clinical research can begin, the study must gain approval of its study protocol. A study protocol outlines a study's rationale, objectives, methodology, data collection and analysis, and risk assessment. The review and approval of a study protocol prior to implementation helps to ensure the integrity of the study and the rights of study participants. Inova's Protocol Review and Monitoring Committee approved the study protocol outlining the randomized clinical trial investigating the optimal type of full-body imaging for cancer early detection in September 2024. Following Inova policy, an external IRB operated by WCG reviewed and approved the study protocol in January 2025. The Inova research team worked collaboratively with both approval bodies to address any questions and requested revisions to the study protocol.

With full approval of the study protocol, enrollment into the study began in February 2025. Addressing scheduling considerations for all required study appointments (initial research visit, whole-body imaging procedure, follow-up result visit), the team capped enrollment to 10 participants per week. This number of participants per week was determined to be optimal based on clinical resources available to ensure that the firefighters received timely and comprehensive follow-up consultations on results of their screening examinations.

Study recruitment has been a collaboration between the local firefighter jurisdictions, the Inova firefighter occupational cancer screening and risk assessment clinic within the Saville Cancer Screening and Prevention Center, and Inova's Department of Occupational Health. Interest among regional firefighters has exceeded expectations, and as of summer 2025, the study is working from a waitlist of over 400 firefighters. Given the high interest, the study has paused adding firefighters to the waitlist to ensure all those on the list have the opportunity to be enrolled. Inova plans to reopen the waitlist in early 2026.

The high interest in the study did create some obstacles in the research team's ability to keep up with demand. In response, the research team set up a self-scheduling portal that allows interested firefighters to self-select a date and time for their initial research visit. Then, the team

sends interested firefighters the portal link in batches to align with their NFPA physical exam to ensure the study criteria of having had their exam within 6 months is still met. In addition, to help accommodate study demand and allow more flexibility with scheduling, the team added a telehealth visit option for the imaging procedure follow-up result visit. This flexibility in scheduling allowed the team to increase enrollment from 10 to 12 per week as of August 2025.

By the end of June 2025, the study had enrolled 195 firefighters, with 195 having completed the MCD assay, 88 completed whole-body MRI, and 76 completed whole-body ultrasounds. Four firefighters were disenrolled from the program as of June 2025 due to them having completed prior imaging within 1 year of the study. Seven cancers have been diagnosed through the screening program (3 skin cancers and 4 solid tumors) among participants that were enrolled through June 2025 and have had their results reviewed (5.3% cancer detection).

The clinical team at Inova and the regional firefighter jurisdictions in Planning District 8 have developed and strengthened a strong relationship including through regular meetings between the leadership of the departments and through Inova team member ride-alongs and fire station site visits. The Inova team has been recognized for the occupational screening clinic with the Food on the Stove's (a non-profit focused on firefighter health) 2025 Community Health Partner Award, and by regional fire chiefs who presented the clinical research team with a departmental appreciation coin in summer 2025.

REQUIRED MATCH

As outlined in Budget Item 272 (H), Inova Heath system is required to match or exceed the annual funds appropriated ($430,000) for this pilot program. In FY2025, Inova contributed $551,948 to the pilot program, including $270,996 for personnel costs of the Inova research team, $47,092 for overhead administrative costs, and $233,860 for clinical procedures and visit costs. Inova's estimated match for FY2026 totals $1,736,919 ($292,006 personnel, $1,310,736 clinical procedures and visits, $45,000 DSMB, $89,177 overhead). Over the course of the study, Inova's contribution will total more than 2.2 million.

NEXT STEPS

From July 1, 2026 until the next report in Spring 2028, VDH and Inova anticipate the following activities will occur:

- Inova will enroll an additional 605 firefighters to reach the trial goal of 800
- Inova will work with enrollees to complete MCD assay, whole-body MRI, and whole-body ultrasound screenings for all enrolled firefighters
- Inova will provide an interim report in Spring 2027 to include preliminary results from all screened. This will not include results on 1-year follow-ups, as they will still be ongoing.
- Inova will work to expand the Community Advisory Committee to include representation from the Virginia Department of Fire Programs and/or other Virginia health systems to help address the applicability of the study to be replicated in other communities in the Commonwealth.
- The DSMB will provide independent oversight of the firefighter occupational cancer screening pilot program and associated clinical trial, to include routine review of study data and progress.
- Inova and VDH will publish final results of the pilot program and associated clinical trial in Spring 2028

APPENDIX A – CHAPTER 2 OF THE 2024 ACTS OF ASSEMBLY (BUDGET BILL), ITEM 2752 (H)

H.1. Out of this appropriation, $430,000 the first year and $430,000 the second year from the general fund shall be provided to the Virginia Department of Health to implement the Northern Virginia Firefighter Occupational Cancer Screening Pilot Program. Funding shall be contingent on the demonstration of an equal amount of matching funds each year provided by a health system-affiliated cancer screening center that has a contractual agreement to conduct the pilot program.

2. The pilot program shall be designed to (i) contract with a health system-affiliated cancer screening center located in Planning District 8 to implement the pilot program, (ii) be multi-year, and (iii) screen at least 450 firefighters annually, distributed among firefighters serving localities in Planning District 8. The design of the pilot program should include: (i) the use of an occupational cancer screening and risk assessment for eligible firefighters within a defined age and risk band; (ii) a randomized clinical trial investigating the optimal type of full-body imaging for cancer early-detection for the unique occupational cancer risk of firefighters; and (iii) an independent evaluation of the pilot program, assessing the effectiveness of the screening program and results of the clinical trials and their potential for use by other hospitals and health systems across Virginia, in partnership with the public safety divisions in their localities.

3. The Virginia Department of Health shall provide an interim report on the pilot program to the Chairs of the House Appropriations Committee and Senate Finance and Appropriations Committee by December 1, 2025 and a report on the evaluation upon completion of the pilot program.

APPENDIX B– ACRONYMS AND ABBREVIATIONS

This is a listing of the acronyms and abbreviations appearing throughout the report and its appendices.

CPT – Current Procedural Terminology

DSMB - Data and Safety Monitoring Board

EMR – Electronic Medical Record

HIPAA – Health Insurance Portability and Accountability Act

IARC – International Agency for Research on Cancer

IRB - Institutional Review Board

MCD – Multi-Cancer Detection

MRI - Magnetic Resonance Imaging

NFPA - National Fire Protection Association

NPV – Negative Predictive Value

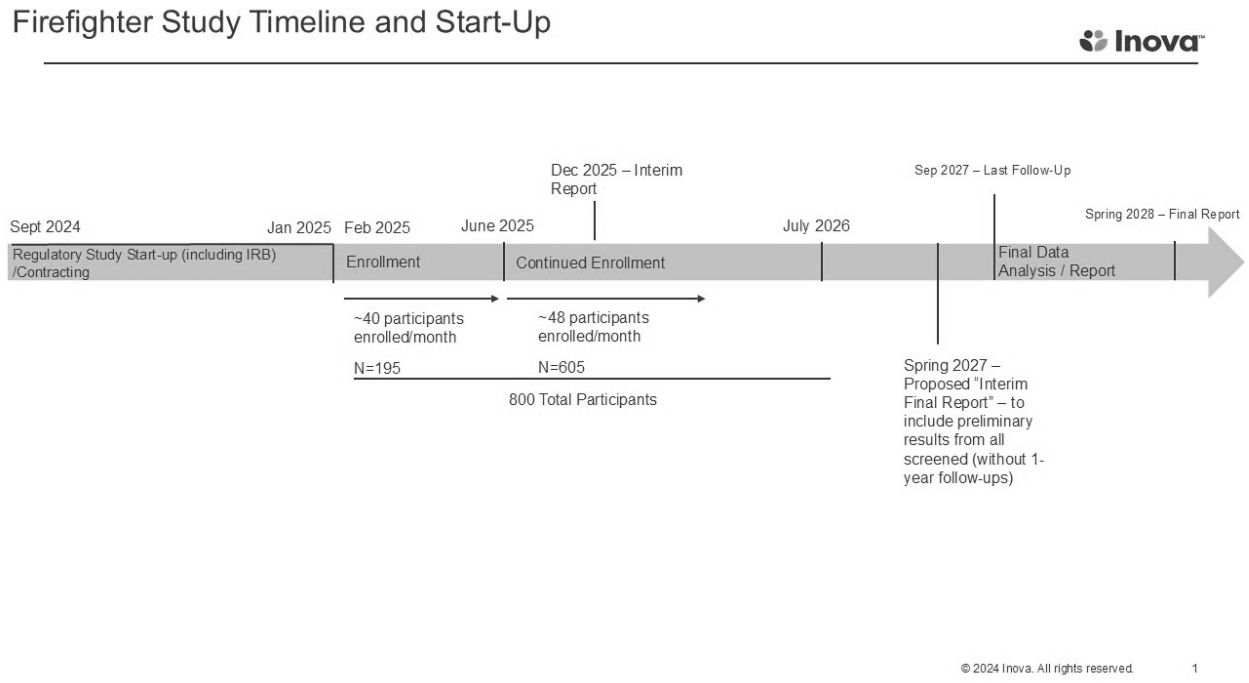
PPV – Positive Predictive Value

STAI - State-Trait Anxiety Inventory

VDH – Virginia Department of Health

APPENDIX C – STUDY TIMELINE

Below is an anticipated study timeline based on progress made through June 2025:



APPENDIX D – DATA FIELDS COLLECTED

Demographics, collected via medical record and research questionnaire:

- Medical record number
- Name
- Date of Birth
- Age
- Biological Sex
- Race
- Ethnicity

Medical/Surgical History and Cancer Screening (yes/no and date of diagnosis or screening), collected via medical record:

- Mammogram screening history
- Pap smear screening history
- Colon cancer screening history
- Total body skin screening history
- Lung cancer screening history
- Other screening tests conducted in occupational exposure clinic (target thyroid ultrasound; VECTRA; colonoscopy/blood stool test; PSA; and/or breast cancer screening)
- Pulmonary Function Test
- Previous Imaging Results
- HPV vaccine
- Genetic testing history
- Comorbid-Pulmonary
- Comorbid-Cardiac
- Comorbid-Endocrine
- Comorbid-Infectious Disease
- Comorbid-Cancer
- Comorbid-Mental Health
- Surgical history
- Current medications
- Laboratory values

Psychological/Lifestyle History, collected via medical record unless otherwise stated:

- Alcohol use
- Physical activity
- Tobacco use
- Drug use
- Environmental exposure
- Firefighter occupational history (research questionnaire)
- Anxiety (research questionnaire)

Family History of Cancer, collected via medical record:

- Family member affected
- Cancer type
- Age at diagnosis

Study procedures, collected via medical record:

- Whole-Body MRI report and findings by organ system
- Whole-Body Ultrasound report and findings by organ system
- MCD testing result

Follow-up, collected via medical record:

- Number, types, and dates of medical visits, diagnostic procedures (including biopsies) needed as a result of study imaging or MCD results through 1-year (± 2 months) follow-up
- CPT codes and associated standard Medicare rates for follow-up diagnostic procedures needed as a result of study imaging or MCD results through 1-year (± 2 months) follow-up
- Diagnosis of cancer (site/stage) and confirmatory pathology report information at end of diagnostic resolution and/or 1-year follow-up.
- Adverse Event

APPENDIX E– STUDY OUTCOMES ANALYZED

Below is a breakdown of the data analysis questions to be answered for each study objective.

Objective 1: To provide preliminary pilot data on the clinical impact of each whole-body imaging procedure and the MCD test in identifying pre-malignancies and malignancies in firefighters.

- Number and type of confirmed pre-malignancies or malignancies detected with each investigational screening tool (whole-body MRI, whole-body ultrasound, MCD test) by the end of diagnostic resolution and at 1 year (± 2 months) follow-up.
- Proportion relative to total screened and PPV of confirmed pre-malignancies or malignancies detected with use of each investigational screening tool (whole-body ultrasound, whole-body MRI, and MCD test) by the end of diagnostic resolution and at 1 year (± 2 months) follow-up.
- Sensitivity, specificity, and NPV of each investigational screening tool if calculable (whole-body ultrasound, whole-body MRI, and MCD test) at 1-year (± 2 months) of follow-up.
- Concordance between the MCD assay and whole-body imaging scan used in each screening arm for identifying a suspected pre-malignant or malignant finding during screening and a confirmed pre-malignancy or malignancy at diagnostic resolution and 1-year (± 2 months) follow-up

Objective 2: To evaluate the follow-up diagnostic evaluations and healthcare utilization associated with each investigational screening tool in firefighters.

- Total proportion of participants requiring any diagnostic follow-up procedures for each screening modality (whole-body ultrasound, whole-body MRI, and the MCD test).
- Proportion of participants with a false-positive result (relative to total screened) for each investigational screening tool (whole-body ultrasound, whole-body MRI, and the MCD test) by the end of diagnostic resolution and at 1 year (± 2 months) follow-up.
- Total number and type of follow-up diagnostic procedures and medical visits and consults required, average time to diagnostic resolution, and the average total cost of this follow-up healthcare utilization for each screening modality (whole-body ultrasound, whole-body MRI, and MCD assay) by the end of diagnostic resolution and at 1 year (± 2 months) follow-up.

Objective 3: To understand the anxiety of firefighters in each screening arm pre- and post-imaging exam.

- Scores from the STAI *within* the same study participants in each screening arm at the time of randomization to a whole-body imaging procedure (pre), following completion of the imaging (post), and after review of imaging results.
- Scores from the STAI *between* study participants in the two screening arms at the time of randomization (pre) and following completion of the imaging (post).

Objective 4: To understand the feasibility of firefighters completing the screening tests, enrolling a diverse population to the pilot study, as well as describing occupational

exposure characteristics, clinical characteristics, and cancer related risk factors of the study population.

- Proportion of participants that complete the MCD screening, and the whole-body imaging procedure relative to all participants randomized to each screening arm.
- Descriptive summary (proportion, mean/medians as appropriate) of participants enrolled in the study with respect to sex, race/ethnicity, type of service (career, volunteer), job titles, and occupational and cancer related exposures.
- Descriptive summary (proportion, means/medians as appropriate) of clinical characteristics of participants enrolled in the study based on an electronic medical record review of medical/surgical history (including laboratory assessments), family history of cancer, and other cancer screening assessments.

APPENDIX F– REFERENCES

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