



Economic Evaluation of STA-Liatest D-Di for Exclusion of Venous thromboembolism (VTE) in ED for the US Healthcare System

Value Proposition

Improved patient outcomes and experience, shorter length of stay and cost reduction drive the recognition of value in today's rapidly-evolving and competitive healthcare environment. Stago contracted with Alira Health to conduct an economic evaluation comparing the use of the STA-Liatest D-Di assay in conjunction with a probability assessment model to other D-dimers.



Authors

Alira Health

Alira Health is an international advisory firm providing integrated strategy, execution and innovation services for healthcare and life science companies. Our strategists, bankers, doctors and scientists collaborate to fully understand every aspect of healthcare.

Our HEOR (Health Economics and Outcomes Research) expertise represented by our team of clinicians, health economists, and consultants work closely with regulatory, payer, and marketing experts to target economic and financial value.

At Alira Health, our HEOR studies focus on translating the clinical and technical benefits of a technology with economic evidence that keeps the entire healthcare system in perspective. We conduct health economics as defined in section 502(a) as “any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.”

Alira Health's Approach to HEOR



Burden of Illness

HEOR generates evidence to prove clinical, economic and societal burden of diseases from multiple perspectives.



Economic Evaluation

HEOR develops real world health economic models backed by sound clinical evidence.



Clinical Pathway Validation

HEOR determines how changes in treatment can influence clinical scenarios and determine patient outcomes.



Health Economic and Economic Research (HEOR)

HEOR develops patient focused health economic studies, which establishes clinical and economic evidence for the given clinical conditions and indirect and mixed treatments.

Overview on Stago

With a staff close to 2,600 and the most advanced technologies, Stago formulates, manufactures and markets the broadest range of reagents and analytical instruments in Haemostasis, worldwide. Stago devotes its research and innovative skills to the development of increasingly effective medical diagnostic products and instrumentation.

Stago Group has acquired its expertise over many years, accompanying, and often leading, the rapid growth of this Haematology-related scientific discipline – Haemostasis. Today, Stago is the only independent international group in the *in vitro* diagnostics industry dedicated to Haemostasis and Thrombosis exploration.

See section 502(a), as amended by section 114 of FDAMA and section 3037 of the 21st Century Cures Act. As used in this guidance, the term “section 502(a)” refers to the part of that section specific to HCEI

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INTRODUCTION

WHAT IS VENOUS THROMBOEMBOLISM?

Venous thromboembolism (VTE), which consists of deep vein thrombosis (DVT), a blood clot in a deep vein in the body, and pulmonary embolism (PE), the dislodgement of the clot and its passage into the lungs, is an important public health concern causing considerable morbidity and mortality.

Studies estimate that 10%–30% of all patients suffer mortality within 30 days; most deaths occur among those with PE, as an estimated 20%–25% of all PE cases present as sudden death [2]. Other serious complications of VTE include increased risk of recurrent thromboembolism and chronic morbidity (e.g., venous insufficiency, pulmonary hypertension).

INCIDENCE AND DIAGNOSIS

The overall annual incidence of VTE in the U.S. is estimated to be between 1 and 2 per 1000 people, or 300,000–600,000 cases [1,2,3]. About two thirds of patients with VTE present for care with DVT, and the remaining one third present with PE. In the US, approximately 50% to 70% of VTE patients are diagnosed in the Emergency Department (ED) of which, 60% have DVT and 40% have PE.

Stago Group conducted an international, multicenter, prospective nonrandomized, noninterventional clinical outcome management study, following the Clinical and Laboratory Standard Institute guideline (CLSI H59-A "Quantitative D-Dimer for the exclusion of venous thromboembolic disease; approved guideline). The study established a negative predictive value (NPV), sensitivity and specificity of 100%, 100% and 55.2% for DVT exclusion and 99.7%, 97.0% and 75.5% for PE exclusion, respectively [2, 64].

VTE COST TO HEALTHCARE IN THE US

Although data are lacking on the exact cost attributed to VTE, a recent analysis of healthcare claims estimated that the total annual healthcare cost for VTE ranges from \$7594 to \$16,644 per patient. With estimates of 300,000–600,000 incident cases per year, the cost equates to a yearly total of \$2 billion to \$10 billion attributable to VTE [7].

STA-LIATEST D-DI ASSAY

STA-Liatest D-Di assay demonstrates excellent performance when used in combination with a clinical score in relevant patients and has the potential to minimize the economic healthcare burden avoiding unnecessary and expensive imaging tests, improving patient experience through a faster diagnosis, decreasing complications and reducing overcrowding of EDs [2, 47].

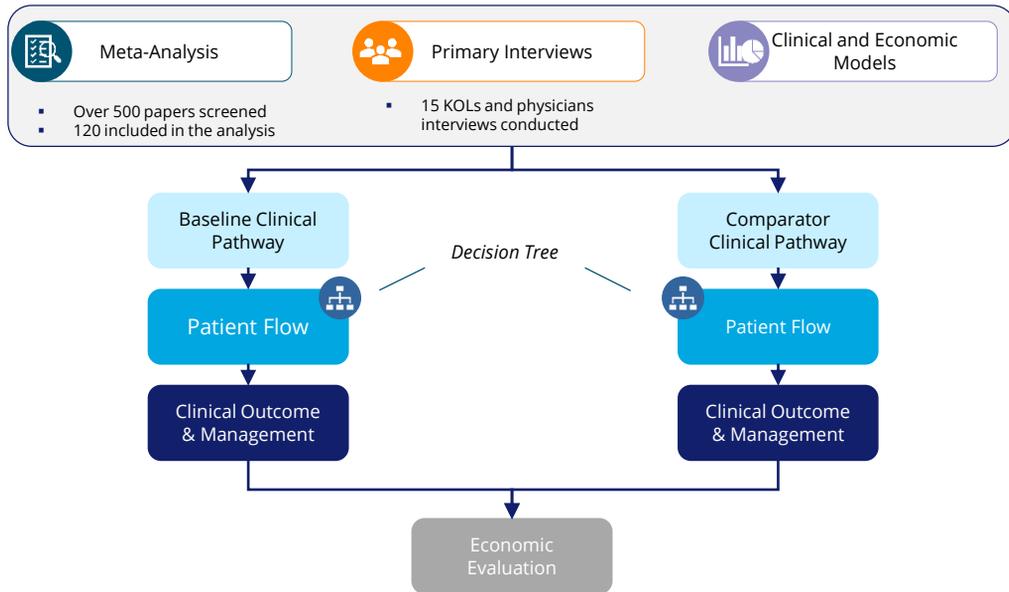
HEALTH ECONOMICS

We conducted a **health economic analysis**, comparing the use of **STA-Liatest D-Di assay** for **the exclusion of VTE in patients with low/moderate pre-test probability (PTP)**, as defined in 2018 **ASH guideline** [24], with current **standard-of-care** and other FDA approved D-dimer assays for similar indications.

METHODOLOGY

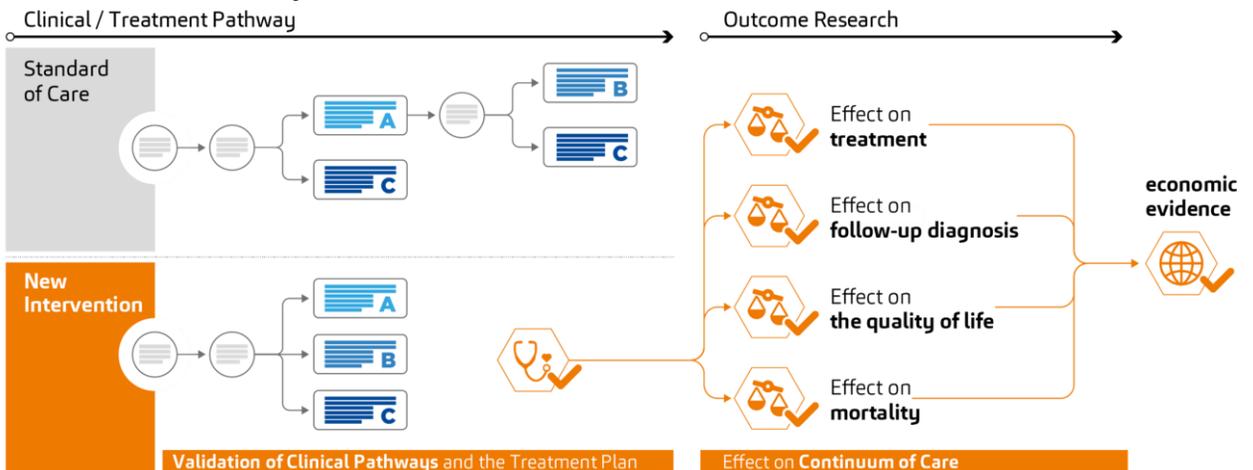
SYSTEMATIC REVIEW

We conducted a systematic review of the literature by searching PubMed, Scopus, Ovid, and MEDLINE databases from January 2000 to December 2018 for studies comparing diagnostic costs, treatments, clinical pathways, outcomes, and hospitalization burden associated with management of VTE patients presented to ED in the US. The following types of studies were included: 1) prospective, randomized controlled trials that included VTE patients; 2) systematic reviews, including meta-analyses, focused on the diagnosis, treatment and outcomes of VTE patients; 3) studies evaluating burden of hospitalizations, ED overcrowding, morbidity and mortality associated costs; and 4) studies examining health care models to evaluate financial impacts of evolving guidelines for VTE diagnosis.



ECONOMIC EVALUATION

The economic evaluation was performed according to the definition of Health Care Economic Information (HCEI) as defined in section 502(a), as amended by section 114 of FDAMA and section 3037 of the 21st Century Cures Act.

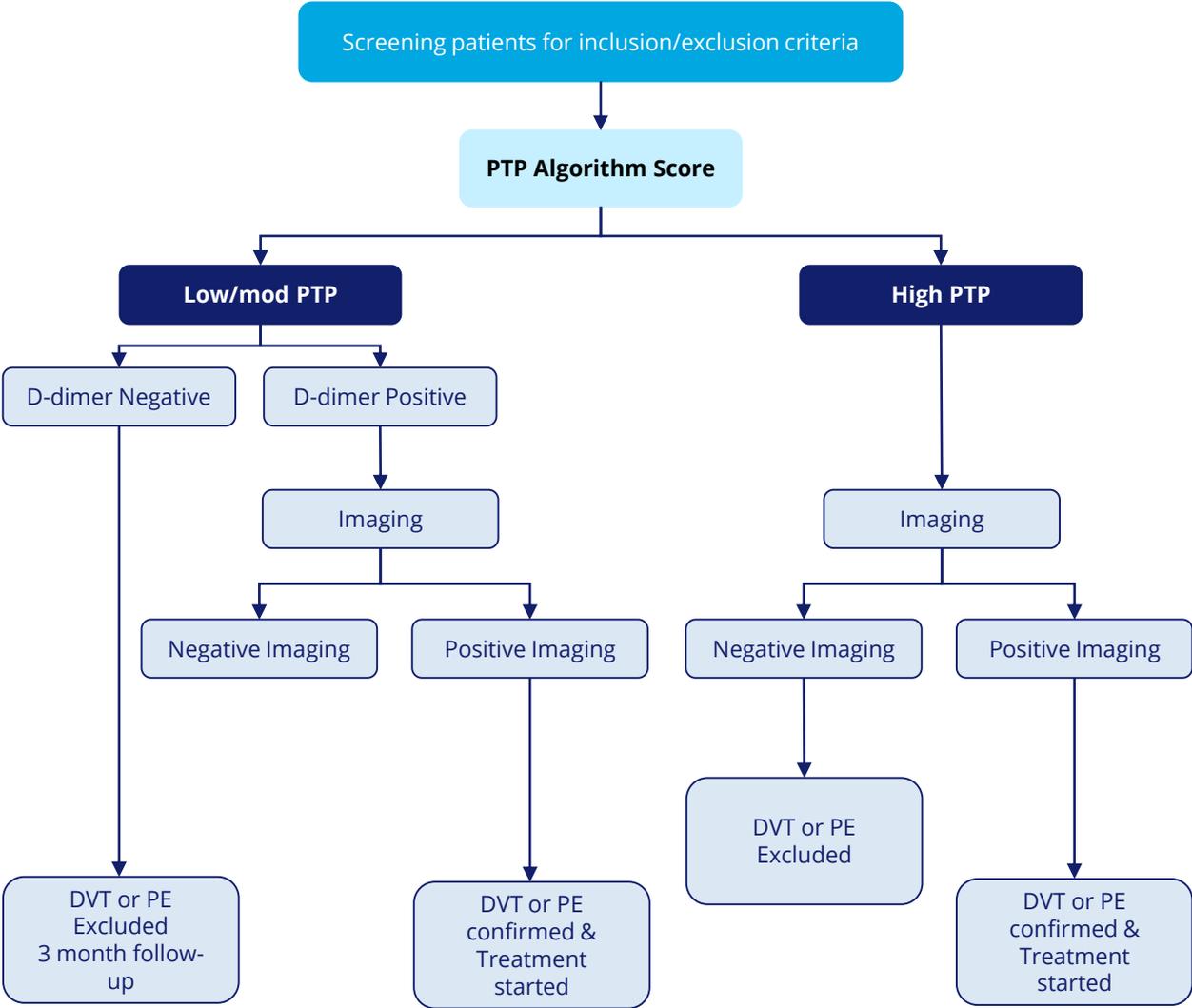


ECONOMIC EVALUATION OF STA-LIATEST D-DI FOR EXCLUSION OF VTE

CLINICAL PATHWAY

Guidelines for management of venous thromboembolism such as American Society of Hematology 2018 guidelines [24] concluded that for patients at low (unlikely) VTE risk, using D-dimer as the initial test reduces the need for diagnostic imaging. For patients at high (likely) VTE risk, imaging is warranted¹. For PE diagnosis, ventilation perfusion scanning and computed tomography pulmonary angiography are the most validated tests, whereas lower or upper extremity DVT diagnosis uses ultrasonography. The economic impact of using STA-Liatest D-Di assay for the exclusion of VTE in patients with low/moderate clinical probability (DiET Study NCT01221805) has been compared with imaging alone for DVT and imaging and D-dimer simultaneously for PE for outpatients suspected of PE or DVT .

DiET Study NCT01221805



Note: ¹In the case of PE, D-Di for intermediate PTP patients is recommended if results can be obtained in a timely manner.

ECONOMIC EVALUATION OF STA-LIATEST D-DI FOR EXCLUSION OF DVT

HEALTH ECONOMIC ANALYSIS (DVT)

STA-LIATEST D-DI ASSAY AS in DiET Study NCT01221805 VS STANDARD OF CARE (IMAGING)

Care Pathway N°1 – Imaging only

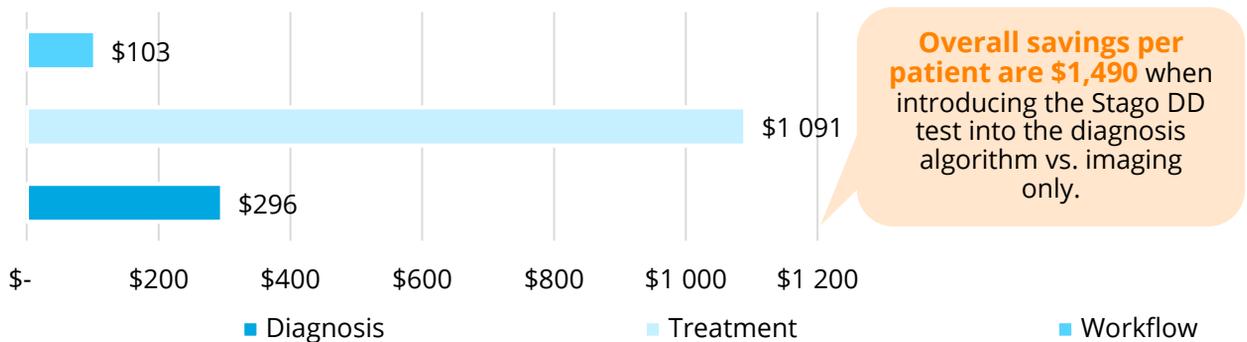


Vs.

Care Pathway N°2 – Imaging + DD



Average savings per patient of Stago (care pathway N°2) vs. imaging only (care pathway N°1), on a basis of 100 patients presented to the ED with DVT prevalence of 22.1%, savings categorized into diagnosis, treatment and workflow related.



STA-LIATEST D-DI ASSAY AS in DiET Study NCT01221805 VS COMPETITORS

Care Pathway N°2 – Imaging + DD- Stago

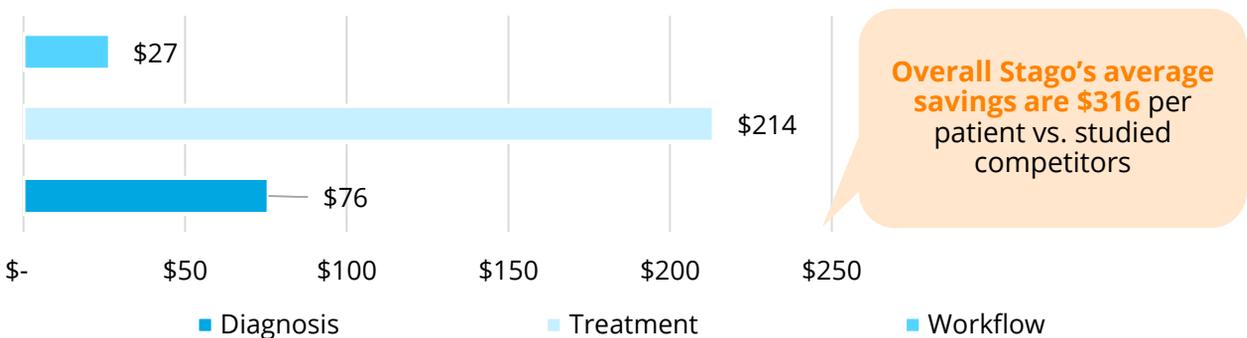


Vs.

Care Pathway N°2 – Imaging + DD- Competitors



Average savings per patient of Stago (care pathway N°2) vs. competitors (care pathway N°2), on a basis of 100 patients presented to the ED with DVT prevalence of 22.1%, savings categorized into diagnosis, treatment and workflow related.



Average savings split by competitors



Vs.



PTP



Imaging



D-dimer

+ Test Combinations

ECONOMIC EVALUATION OF STA-LIATEST D-DI FOR EXCLUSION OF PE

HEALTH ECONOMIC ANALYSIS (PE)

STA-LIATEST D-DI ASSAY AS RECOMMENDED IN DiET Study NCT01221805 VS STANDARD OF CARE

Care Pathway N°2 – Imaging+DD simultaneously

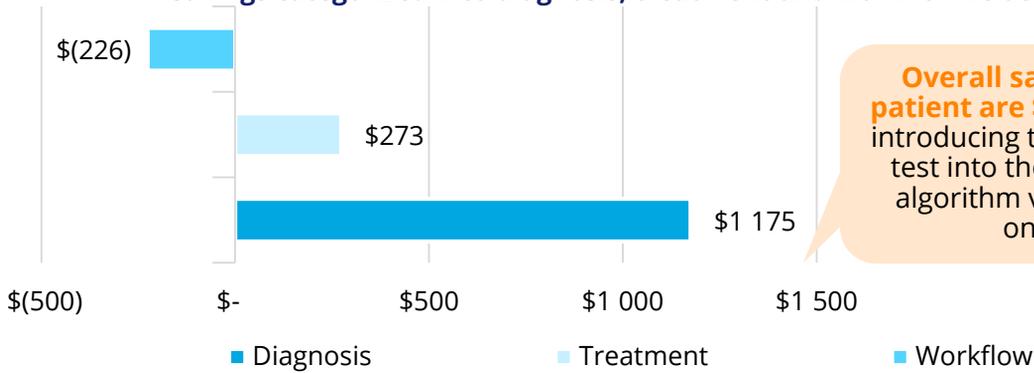


Vs.

Care Pathway N°3 – 2018 ASH



Average savings per patient of Stago (care pathway N°2) vs. imaging and D-dimer in parallel (care pathway N°1), on a basis of 100 patients presented to the ED with PE prevalence of 7%, savings categorized into diagnosis, treatment and workflow related.



Overall savings per patient are \$1,233 when introducing the Stago DD test into the diagnosis algorithm vs. imaging only.

STA-LIATEST D-DI ASSAY AS in DiET Study NCT01221805 VS COMPETITORS

Care Pathway N°3 – Imaging + DD- Stago

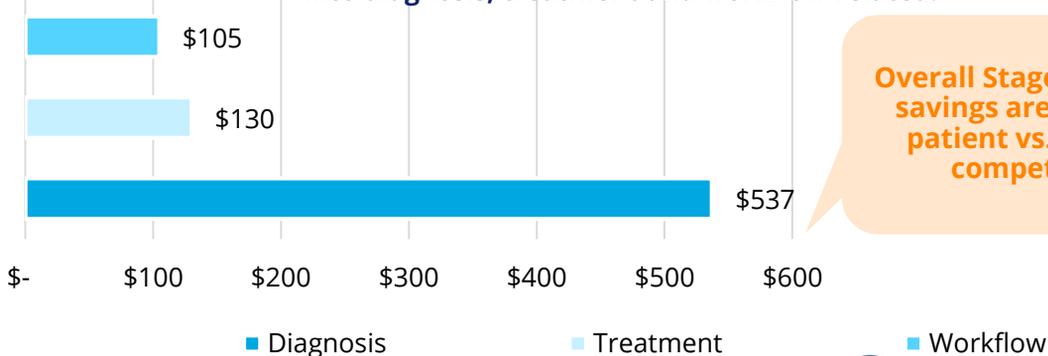


Vs.

Care Pathway N°3 – Imaging + DD- Competitors



Average savings per patient of Stago (care pathway N°3) vs. competitors (care pathway N°3), on a basis of 100 patients presented to the ED with PE prevalence of 7%, savings categorized into diagnosis, treatment and workflow related.



Overall Stago's average savings are \$772 per patient vs. studied competitors

Average savings split by competitors



Vs.



+ Test Combinations

VALUE PROPOSITION OF STA-LIATEST D-DI

GENERAL VALUE PROPOSITION

Health care reimbursement models are transitioning from volume-based to value-based models. Value-based models focus on patient outcomes both during the hospital admission and post discharge. These models place emphasis on cost, quality of care, and coordination of multidisciplinary services and continuum of care.

Overall imaging savings to the US healthcare system is ~ \$620M a year for VTE patients categorized in low / moderate clinical probability, as ~820,000 patients can safely be ruled out with STA-Liatest D-Di test avoiding unnecessary imaging if the diagnostic triage as presented in DiET Study NCT01221805 is followed.

With no differences in diagnostic efficacy, the diagnostic triage presented in DiET Study NCT01221805 may be considered a dominant strategy, i.e. giving the same result at a lower cost.



Reduced delay and overcrowding in the ED.



Improved patient experience through a **faster diagnosis / decreased risk of complications.**



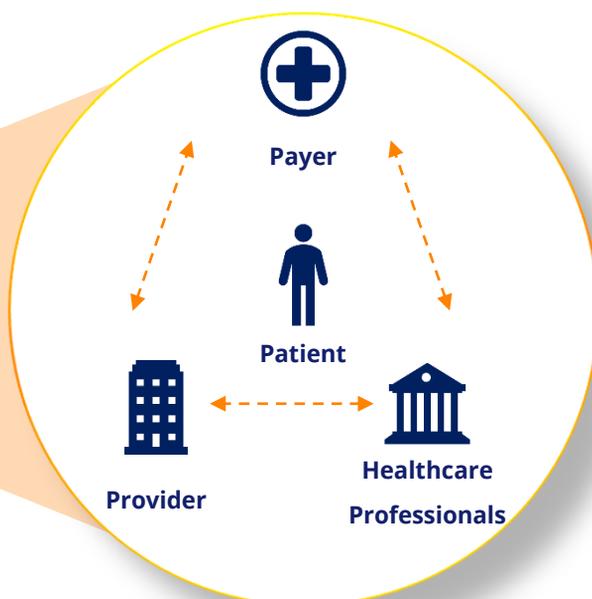
Avoided unnecessary imaging associated with a small but significant **risk of complications.**



Validated by **FDA for exclusion** of VTE in patients with low to moderate risk as per CLSI H59-A guidelines.



STA-Liatest D-Di



VALUE PROPOSITION OF STA-LIATEST D-DI

VALUE PROPOSITION- PATIENT

820.000 VTE patients with low/mod PTP can **safely be ruled out** annually with Stago's D-dimer test and **avoiding imaging and its related diagnosis complications.**



Improved patient experience through a **faster diagnosis**



Avoided unnecessary imaging associated with a small but significant **risk of complications**, among low probability patients



Avoided unnecessary waiting time in the Emergency Department

Savings related to **avoiding complications** by introduction of Stago's D-dimer test in the diagnosis pathway for **VTE**



~\$770/ VTE patient



~\$382/ VTE patient



~\$512/ VTE patient



~\$412/ VTE patient



~\$363/ VTE patient



In a multi-center international clinical study conducted according to CLSI H59-A guideline at multiple sites in the United States, Europe and Canada, STA-Liatest D-Di has demonstrated its ability to safely exclude DVT in conjunction with a clinical pretest probability assessment in more than 2000 outpatients with low to moderate risk of VTE.

VALUE PROPOSITION OF STA-LIATEST D-DI

VALUE PROPOSITION – HEALTHCARE PROFESSIONALS

\$76M annual savings of **HCP costs**, linked to the number of low/mod PTP VTE patients safely ruled out with DD and avoided imaging



Reduced number of ultrasounds decreasing physician related costs



Increased physician availability

Savings related to HCP costs in the United States



~\$76M
year savings



~\$38M
year savings



~\$51M
year savings



~\$42M
year savings



~\$38M
year savings



In a multi-center international clinical study conducted according to CLSI H59-A guideline at multiple sites in the United States, Europe and Canada, STA-Liatest D-Di has demonstrated its ability to safely exclude DVT in conjunction with a clinical pretest probability assessment in more than 2000 outpatients with low to moderate risk of VTE.

VALUE PROPOSITION OF STA-LIATEST D-DI

VALUE PROPOSITION – HEALTHCARE PROVIDERS

\$82M savings of ED costs per year, linked to better diagnostic management of low/mod PTP patients*



Reduced delay and overcrowding in the ED



Reduced number of ultrasounds decreasing physician related costs



Increased physician availability

Savings related to introduction of Stago's D-dimer test in the diagnosis pathway for **VTE**



~\$82M
year savings



~\$11M
year savings



~\$55M
year savings



~\$22M
year savings



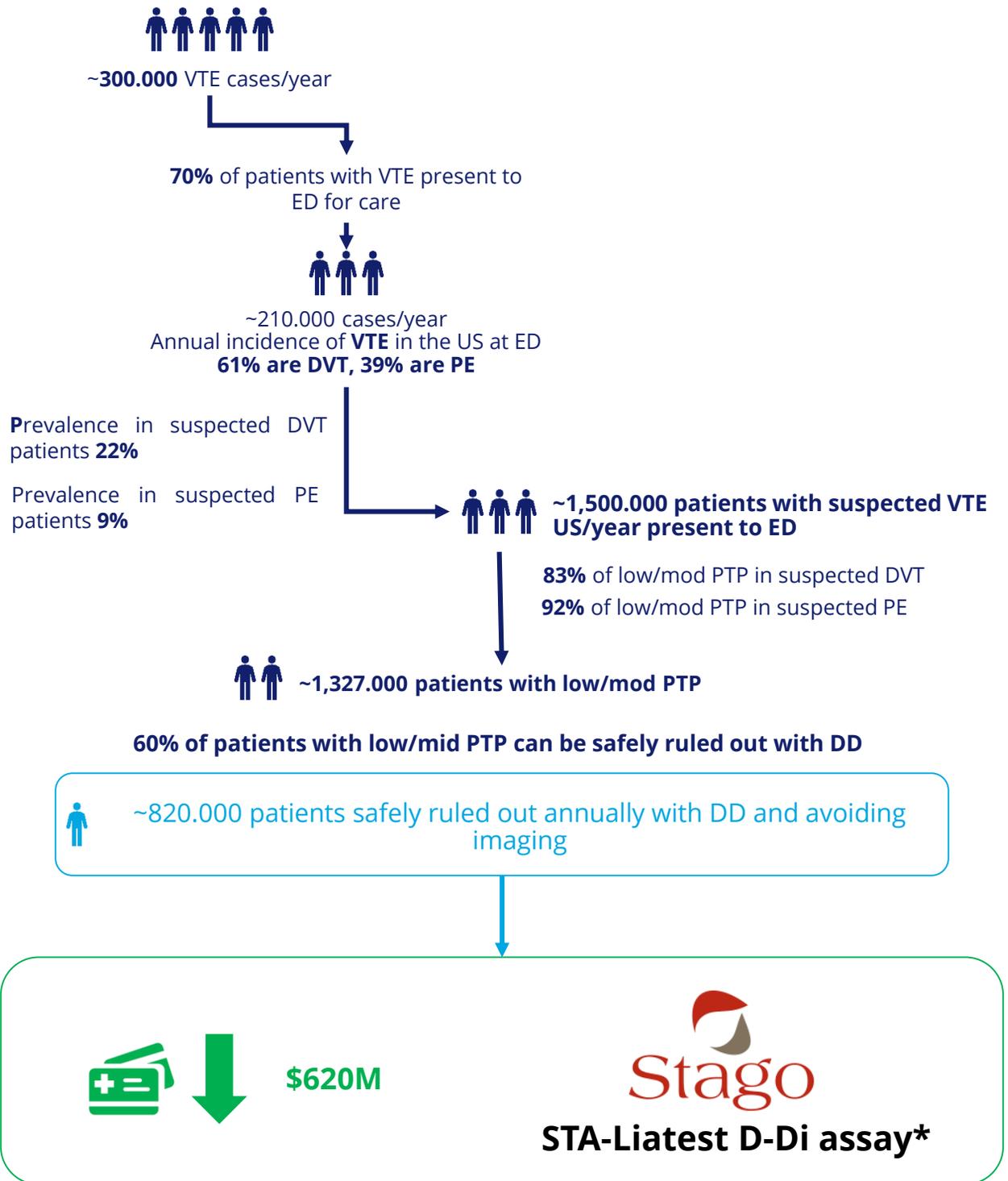
~\$20M
year savings



In a multi-center international clinical study conducted according to CLSI H59-A guideline at multiple sites in the United States, Europe and Canada, STA-Liatest D-Di has demonstrated its ability to safely exclude DVT in conjunction with a clinical pretest probability assessment in more than 2000 outpatients with low to moderate risk of VTE.

ECONOMIC EVALUATION OF STA-LIATEST D-DI FOR EXCLUSION OF VTE

SAVINGS FOR THE HEALTHCARE SYSTEM



Note: *The savings were calculated using the pathway described DiET Study NCT01221805.

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