

## Backgrounder

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### Glossary

**Anticoagulant therapy (blood thinning medication):** Medications that delay blood clotting, prevent formation of new blood clots or prevent the enlarging of existing clots. They are sometimes referred to as ‘blood thinners’ although they do not actually thin the blood. People with atrial fibrillation or replacement heart valves are prescribed anticoagulants to reduce the risk of stroke.

**Atrial fibrillation (AF):** A disorder of heart rate and rhythm in which the upper heart chambers (atria) beat more rapidly (quiver) than the lower section of the heart. This results in blood being pumped into the ventricles in a disorganized manner. Because blood is not pumped out completely during beating, it may pool and form a clot. If a section of clot dislodges from the atria and becomes lodged in the brain, a stroke results.

**Contraindication:** A specific circumstance, especially any condition of disease, which renders the use of certain treatments harmful or undesirable.

**Deep vein thrombosis (DVT):** Formation of a blood clot (thrombus) in a deep vein, usually in the pelvis, thigh or calf, but also less commonly in the arm, chest or other location. This can happen if the vein is damaged or if the flow of blood slows down or stops, and can result in two serious complications. Chronic pain and swelling can result if the thrombus blocks the flow of blood through the vein, leading to damage to the blood vessels, and affecting the individual’s ability to lead an active life. If a fragment of the thrombus breaks loose and travels to the lungs, it may block a pulmonary artery or one of its branches, resulting in a pulmonary embolism – a potentially fatal condition.

**Dose-ranging study:** A clinical trial in which two or more doses of a drug are tested against each other to determine the optimal clinical dose.

**Drug–drug interaction:** A modification of the effect of a drug when administered with another drug. The effect may be an increase or decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug alone.

**Efficacy:** The ability of a drug or treatment to produce the desired beneficial effect (independent of potency – the amount of the drug necessary to achieve the desired effect).

**Low molecular weight heparin (LMWH):** Subcutaneous (injected under the skin) anticoagulant used in individuals with deep vein thrombosis to prevent new clots forming and prevent existing clots from getting larger. Lovenox/Clexane (enoxaparin, Sanofi-Aventis) is the current global gold standard in VTE prevention.

**Parenteral:** Administration of a substance by injection, including subcutaneous (under the skin), intravenous (within a vein), and intramuscular (within a muscle).

**Phase I clinical trials:** Very early studies to determine the metabolism and pharmacological actions of drugs in humans, the side-effects associated with increasing doses, and to gain early evidence of effectiveness. Phase I trials are usually small – recruiting approximately 10–20 participants, and may include healthy volunteers and/or patients.

**Phase II clinical trials:** Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side-effects and risks. Phase II trials recruit a larger number of participants, with a sample size ranging from a few dozen to a few hundred.

**Phase III clinical trials:** Expanded controlled and uncontrolled trials to determine the long-term benefits of the treatment being studied. Phase III studies are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit–risk relationship of the drug and provide an adequate basis for extrapolating the results to the general population. These trials include a large sample size, ranging from a few hundred to a few thousand participants.

**Pulmonary embolism (PE):** Sudden blockage in a lung artery, usually due to a blood clot that moved from the leg. PE is a potentially fatal condition that can result in permanent damage to the lung, and low oxygen levels in the blood, leading to damage to other organs. Symptoms include acute onset of shortness of breath, chest pain, and rapid heart rate and respiratory rate. Some individuals may have haemoptysis (coughing up blood).

**Stroke:** Damage to the brain resulting from oxygen starvation of the brain tissues. Stroke caused by blood clots or other obstructions (ischemic stroke) accounts for 80% of all cases. Blood supply to the brain is interrupted, depriving the cells of oxygen and other nutrients. After a stroke, patients may have difficulty talking, walking and performing other basic tasks. In certain conditions, the risk of stroke can be reduced by anticoagulation.

**Unfractionated heparin (UFH):** (aka heparin) Parenteral anticoagulant that inhibits thrombus and clot formation by blocking the conversion of prothrombin to thrombin, and fibrinogen to fibrin, the final steps in the clotting process. Dose adjustment by weight and regular monitoring are required.

**Unstable angina (UA):** Angina is a specific type of chest discomfort caused by inadequate blood flow through the blood vessels of the heart. Unstable angina refers to new onset of anginal chest pain or prior/existing angina that is increasing in severity, duration or frequency. This condition can quickly lead to a heart attack, especially if associated with certain electrocardiogram changes.

**Venous thromboembolism (VTE):** any thromboembolic event occurring within the venous system, including deep vein thrombosis (DVT) and pulmonary embolism (PE).

Sydney, August 8, 2005

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