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IS YOUR CHOLESTEROL A PROBLEM?

By American Heart Association News

New guidelines offer specific recommendations to treat and prevent high cholesterol. Working with your health care provider is the only sure way to know whether you need treatment, but here are general recommendations:

BE ALERT EARLY

Take a "lifespan" approach to lower heart disease risk, stroke and other major problems. If there's a family history, it's reasonable to test kids as young as 2.



KEEP MONITORING

People between 40-75 are the most likely to need medicine. Among the many factors that could further increase risk:

- family history of heart disease or stroke
- high triglycerides
- metabolic syndrome
- chronic kidney disease
- chronic inflammatory conditions, such as rheumatoid arthritis, psoriasis or HIV
- history of pre-eclampsia or early menopause
- ethnicity



FOCUS ON LIFESTYLE

Healthy eating and physical activity are proven to lower LDL cholesterol (the "bad" kind).



MONITOR

People over 20 who don't have cardiovascular disease should have a risk assessment every 4-6 years.



YOUR GENETICS MATTER

Talk to your doctor. Some populations are more prone to certain medical conditions and could have racial and/or ethnic features that could influence risk. Tools used for risk assessment are not always able to provide accurate information about all populations or individuals.

Source: American Heart Association
Published Nov. 10, 2018

INVESTIGATOR'S BROCHURE

Investigational Product
Compound Number:

Chemical or Approved Generic Name

Trade Name (if applicable)

Effective Date: DD-MMM-YYYY

Previous Version Number	Effective Date

Author	Department	Company

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Roles and Responsibilities

- Roles and responsibilities have not been formally described in the ICH-GCP guidelines. Their role remains vague and ill defined.
- CRC responsibilities vary greatly from institution to institution.
- Responsibilities depend on what is delegated by the Investigator.

Version: Final 24-Mar-2010

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7. Investigator's Brochure

7.2 一般的事項

• 届出以下の要素を含む

- サイトマップ
- 主要な試験結果
- 主要な試験結果の概要
- 試験の目的
- 試験の組織
- 試験の倫理
- 試験と関係する他のガイドライン

ICH GCP guideline

1. Glossary

Common language for investigators/sponsors/ethics committees

2. Principles of Good Clinical Practice

13 tenets of ICH GCP

3. Requirements for IRB/IEC

Roles responsibilities and composition

When new relevant information for the clinical assay becomes available, it should be communicated to researchers and possibly for institutional revision plates (IRBs) before a programmed IB review. Orientation should also be provided to the Clinical Researcher on the recognition and treatment of potential firm and adverse reactions based on the previous human experience and in the pharmacology of the investigation product. [1] The sponsor is responsible for keeping information in the updated IB. Information included in the investigator leaflet should be concise, simple, objective, balanced, non-promotional, allowing an impartial understanding, and facilitate an assessment of risk benefits for the adequacy Of the proposed study. In the IBS subsequent, non-clinical data can be concepts and clinical data can be added. If the product of investigation is marketed and its pharmacology is widely understood by doctors, an extensive investigator leaflet may not be necessary. A hopeful evaluation is necessary to be conducted by the sponsor in each "suspected" to determine the accelerated report of unexpected serious adverse reactions (Sarsars). Although IB also meets other proposals, it is mainly written to enable researchers to carry out clinical studies to assess the risks and benefits associated with an investigatory product. Its purpose is to provide researchers and other stakeholders involved in the judgment with the information to facilitate their understanding of the reasons and main characteristics of the protocol, such as dose, frequency / dose interval, methods of administration procedures Security monitoring and monitoring. It also provides background material to support the clinical management of study participants. Any change in RSI is a change for risk benefit relationship for The summary of data and guidance for the The section must provide the researcher with a clear understanding of the possible risks and adverse reactions, and the specific tests, observations and precautions that may be required for a clinical assay. Generally, the sponsor is responsible for ensuring that an updated IB is made available to the investigator (s) and researchers are responsible à €

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