

Essais cliniques en cancérologie

Pré-requis à la recherche clinique

La majorité des essais cliniques en cancérologie concerne l'évaluation d'un médicament expérimental : lorsqu'une molécule est sélectionnée, elle est tout d'abord expérimentée dans le cadre de la **recherche « préclinique »** (sur le modèle cellulaire ou animal,...). Cette phase est un prérequis indispensable pour étudier la pharmacocinétique du candidat médicament, sa métabolisation par l'organisme vivant et ses toxicités éventuelles. Si le candidat médicament satisfait aux exigences de la recherche pré-clinique (peu de toxicité, bonne métabolisation,...), l'étape de la **recherche « clinique »** peut débuter.



Phases des essais cliniques

Les essais cliniques interventionnels comprennent plusieurs étapes consécutives appelées « **phases** », qui sont chacune destinées à recueillir des informations spécifiques sur le nouveau traitement.

Phases	Patients inclus	Objectifs
I	Une à plusieurs dizaines	→ Évaluer la tolérance du traitement → Déterminer l'éventuelle toxicité (effets indésirables) → Visualiser la pharmacocinétique
II	Une à plusieurs centaines	→ Évaluer l'efficacité du traitement → Déterminer la dose optimale du traitement (via la relation dose-effet) → Identifier les principaux effets indésirables (à court terme)
III	Plusieurs centaines à plusieurs milliers	→ Comparer et prouver l'efficacité du nouveau médicament par rapport au traitement de référence (rapport bénéfice/risque) → Recueillir les effets indésirables
IV	Plusieurs milliers	→ Déterminer l'efficacité en conditions réelles d'utilisation → Évaluer la tolérance à grande échelle → Détecter les effets indésirables rares, survenant à long terme ou les complications qui n'auraient pas pu être détectées précédemment (pharmacovigilance)

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M Woodhall



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La mise sur le marché et la distribution du médicament en Afrique noire francophone Baimanai Angelain Poda, 2015-02-01 Cet ouvrage aborde efficacement le droit pharmaceutique en Afrique sous l'angle du droit OHADA et du droit de l'UEMOA. Il s'appuie sur les exemples burkinabè et sénégalais de deux droits historiquement liés au droit pharmaceutique français des années 1954. Consacré au médicament objet de santé et bien marchand particulier, il montre comment la sécurité sanitaire est appréhendée par le législateur dans les pays en développement aussi bien avant qu'après la mise en place sur le marché du médicament. **The Canadian Journal of Gastroenterology**, 2010 **Nova enciclopedia de bioética** Gilbert Hottois, Universidad de Santiago de Compostela, 2005-10-21 Cumulated Index Medicus, 1982 Nouveau Paris Match, 2004-08 **La Presse médicale**, 1986 Les Livres disponibles, 2003 La liste exhaustive des ouvrages disponibles publiés en langue française dans le monde La liste des auteurs et la liste des collections de langue française *La Recherche*, 1988 **Qui est qui en France**, 2013 *Essais cliniques et normes d'éthique de Nuremberg à Helsinki* Mohamed Naceur Krifi, 2024-11-14 Les scandales provoqués par des pratiques inhumaines lors d'expériences médicales ont permis la naissance et l'évolution des normes modernes encadrant et réglementant l'éthique de la recherche biomédicale en général et des essais cliniques en particulier Code de Nuremberg DoH rapport Belmont CIOMS OMS directives des BPC de l'ICH CRO Ces normes ont voulu d'une approche éthique centrée d'abord sur le médecin puis vers le patient puis finalement la transition s'est faite vers une éthique servant les intérêts des industries Leur évolution conceptuelle les controverses soulevées leur caractère non contraignant leur considération par la communauté médicale comme tant trop restrictives pour la pratique de la recherche ont mené à une application incohérente ou inexistante de ces normes Ainsi les violations des règles d'éthique demeurent fréquentes avec de graves préjudices pour les volontaires et les patients On enregistre particulièrement ces dérives non éthiques les accidents graves y afférents et leurs conséquences scandaleuses au cours d'essais cliniques largement industrialisés sous traités et délocalisés chassant ainsi un contrôle réglementaire sérieux Guide d'éthique de la recherche avec des sujets humains : rapport préliminaire Conseil de recherches en sciences naturelles et en génie Canada, Conseil de recherches médicales (Canada), 1996 *Arts & Humanities Citation Index*, 1997 *Éthique de la Recherche et Éthique Clinique* Christian Herve, 1998-05-01 L'amour est prouvé comme révélation de valeur il n'est irrésistible que dans la mesure où son objet lui semble irrésistible Le vécu amoureux apparaît dans son essence comme une expérience spirituelle Mais cette expérience prend sa source dans l'instinct on ne peut aimer qu'un être avec lequel l'union physique est envisageable Cette parenté entre l'amour et la sexualité a inspiré les théses psychanalytiques sur l'identification et la sublimation Il faut comprendre autrement le lien qui rattache la vie religieuse de l'amour son enracinement biologique *Bulletin analytique* Centre national de la recherche scientifique (France), 1956 Malade ou cobaye Robert Flamant, 1994 **Essais cliniques dans les pays du Sud : entre impérialisme éthique et relativisme moral ?** France Bereterbide, 2014-09-01 Nombre de scandales éthiques

ont maill l actualit de la recherche clinique dans les pays du Sud L objet de cet ouvrage est de soutenir que l thique de la recherche peut et doit tre replac e dans son contexte mais que cette contextualisation ne passe pas par la conception de standards thiques moins exigeants dans les pays du Sud mais par un acclimatement ceux ci **Concours m dical** ,1984

Bulletin analytique ,1956 Bulletin signal tique ,1956 **Point de rep ère** ,1999

Decoding **Thique Recherche Essais Cliniques P M**: Revealing the Captivating Potential of Verbal Expression

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