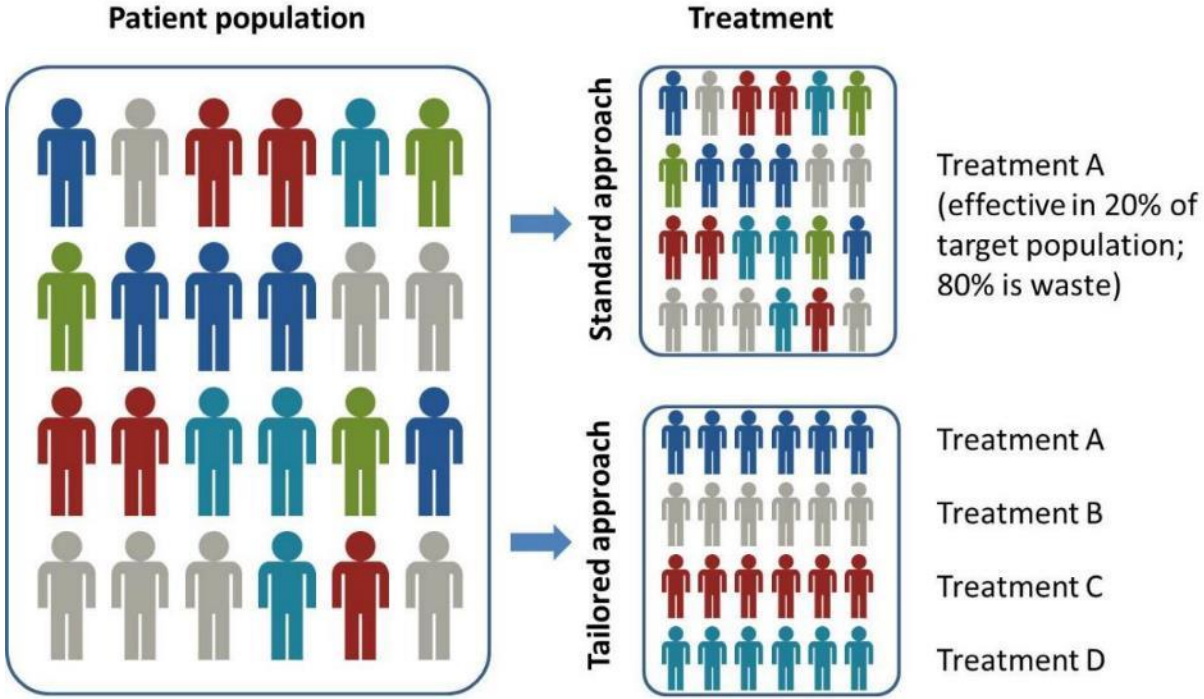
OSLO CANCER CLUSTER

NCE
Norwegian Centres of Expertise

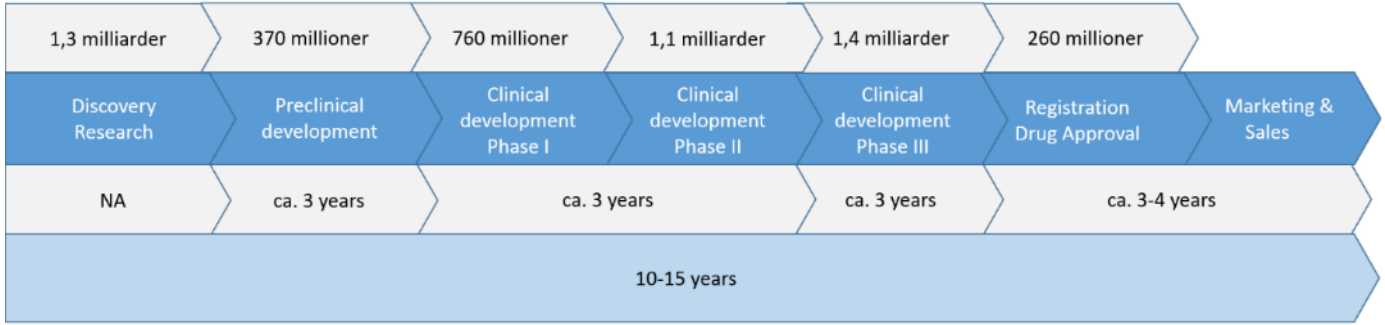
FRA KREFTFORSKNING TIL KUR

Vi er en dedikert pådriver i utviklingen av ny kreftbehandling

DATA ENDRER MEDISIN



GODKJENNING FOR STORE PASIENTGRUPPER



- **Phase I:** evaluate drug safety and tolerability; how the body absorbs and separates the drug, whether it is toxic, and whether the drug has an effect/side effects. Tested in app. 20-150 humans.

- **Phase II:** looks at the medical effects of the drug in patients. Determine when, how, and in what quantities (doses) the drug should be given, and document the most common side effects. Tested in app. 100-200 patients.

- **Phase III:** therapeutic confirmatory phase, seeks to confirm that the drug is safe and effective by the disease and patient group, often compared with the current standard treatment. Tested approximately 100-5000 patients.

LEGEMIDLER I BRUK FØR FASE 3; EKSEMPLER, NÅ TEKNOLOGISK MULIG

Should the FDA Approve More Drugs after Phase II

Matthew Herper

Avik Roy,

Last Friday, *Forbes* health care editor Matt Herper and I sat down to talk about my proposal, which I detailed in a paper for the Manhattan Institute, to encourage the FDA to approve more drugs after mid-stage phase II testing, using a process called "conditional approval." (You can read my proposal, in three parts, here.) Matt put forth some very perceptive critiques of the idea, which I respond to in today's dispatch.

As a refresher, my proposal builds on an existing FDA procedure called *accelerated approval* in which the FDA approves drugs that show great promise in phase II, with the caveat that the drug sponsor must still perform confirmatory phase III studies. If the phase III studies ultimately show that the drug doesn't work as advertised, or has previously unknown safety issues, the FDA can revoke its approval. This is exactly what happened when the FDA revoked the approval of Avastin in breast cancer, after phase III tests did not reproduce the early signal of benefit that the drug had shown in phase II studies.

US Secretary of Health and Human Services Kathleen Sebelius (R) speaks alongside Food and Drug Administration (FDA) Commissioner Margaret Hamburg during the Daily Press Briefing in the Brady Briefing Room of the White House in Washington, DC, June 21, 2011. (Image credit: AFP/Getty Images via @daylife)

The Oncologist

Editorial

Approval After Phase I: Ceritinib Runs the Three-Minute Mile

BRUCE A. CHABNER
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Disclosures of potential conflicts of interest may be found at the end of this article.

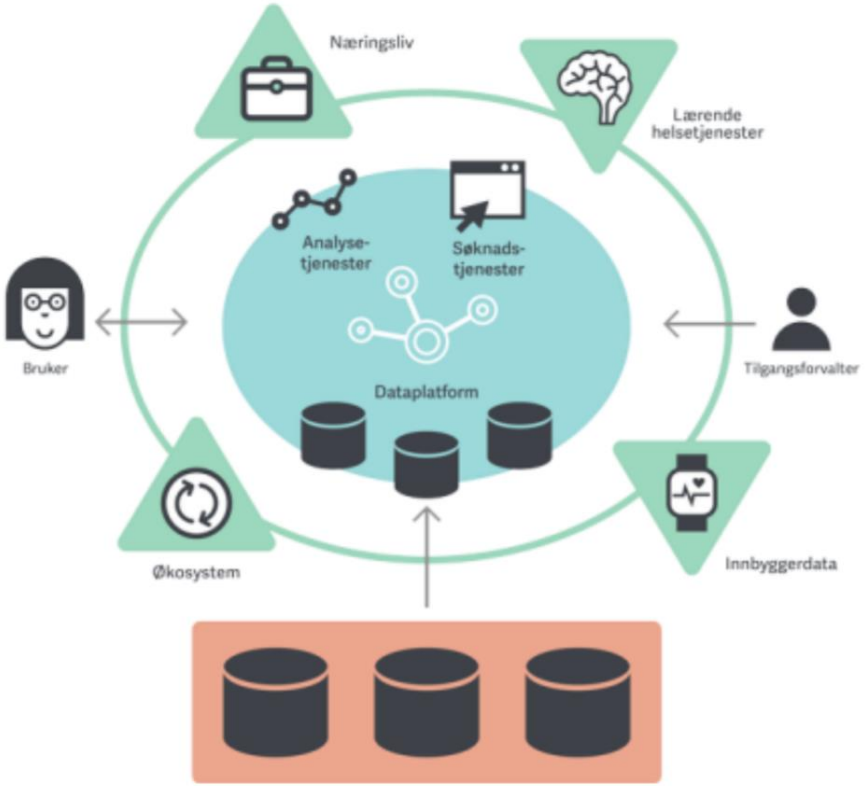
Bruce A. Chabner

Thirteen years ago, I wrote an editorial applauding discovery, development, and marketing approval of imatinib for chronic myelogenous leukemia (CML), a signal event in the history of targeted therapy, and the oncology equivalent of the four-minute mile [1]. It took 3 years from the start of trials and required the confirmatory evidence of two phase II studies to receive the U.S. Food and Drug Administration's (FDA) stamp of conditional approval. A decade later, these pages called attention to the rapid 3-year development of crizotinib for ALK-translocated non-small cell lung cancer (NSCLC), again based explained by its greater potency and its particular ability to inhibit ALK with gatekeeper mutations that confer resistance to crizotinib. In this trial, mechanisms of resistance were characterized in a subset of 19 crizotinib-resistant tumors prior to ceritinib treatment, and responses to the new drug were observed in settings where gatekeeper mutations were present, where ALK was amplified, or where no obvious mechanism was identified. While activation of alternative pathways is suspected of contributing to resistance, particularly when tumors fail to show amplification or mutation

RAPPORT ANBEFALER BRUK AV OFFENTLIGE HELSEDATA TIL DOKUMENTASJON

- Opprette en instans, tilgangsforvalter, som er ansvarlig for tilgjengeliggjøring og markedsføring av helsedata,
- Realisere helseanalyseplattformen rask – denne vil gi tilgang og samtidig sikre personvernet
- Avvikle dagens krav til forhåndsgodkjenning som i enkelte tilfeller forsinker prosjekter med flere år
- Gi muligheten å bruke helsedata som dokumentasjonsgrunnlag for raskere og bedre godkjenning av legemidler.

VI MÅ DOKUMENTERE ETTERSKUDDSVIS



Direktoratet for e-helse

HVA GJØR VI UMIDDELBART?

- Legemiddelinfo inn i Kreftregisteret!
- Etablere analysemetoder og studier for real world data
- Industri/offentlig teste ut «pay for performance» modeller
- Kartlegge alternativ til dagens Markedsføringsgodkjenning

PREKLINIKK - MÅL FRA 6 TIL 1ÅR

UCSF

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Public-Private Consortium Aims to Cut Preclinical Cancer Drug Discovery from Six Years to Just One

Lawrence Livermore National Laboratory, Frederick National Laboratory for Cancer Research, GSK, and UCSF Partner on Effort

By Laura Kurtzman on October 27, 2017

A supercomputer in the Lawrence Livermore National Laboratory, which will be used in a new public-private project to speed discovery of new drug therapies. *Photo by Lawrence Livermore National Laboratory*

Scientists from two U.S. national laboratories, industry, and academia on Oct. 27 launched an unprecedented effort to transform the way cancer drugs are discovered by creating an open and sharable platform that integrates high-performance computing, shared biological data from public and

KLINISKE STUDIER: FRA 10 TIL 5 ÅR?

→ billigere, raskere og mer presise legemidler

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