

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

After Trial, Poor Patients Continued Access to The Drug. Success Story



Reuters

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Disclaimer

- The contents in this presentation are those of the author and do not necessarily reflect the official policy or position of National Hepatology and Tropical Medicine Research Institute (NHTMRI, Egypt), National Committee for the Control of Viral Hepatitis, nor the Egyptian Government.**

□ Countries listen

Research said - How to get more benefit per \$?

“Every \$ invested in health = \$9 of economic benefit! ”

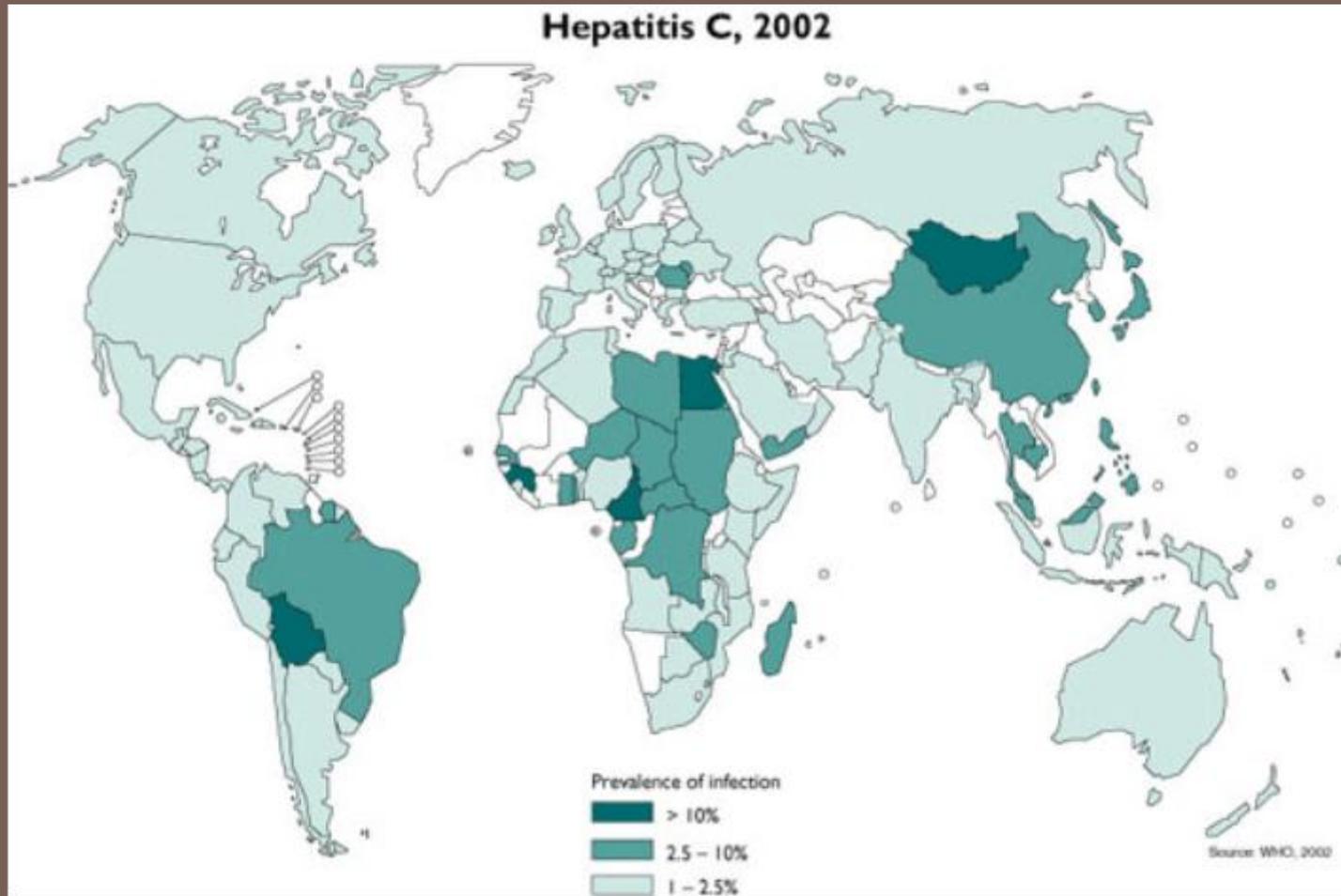
Melinda Gates

Hepatitis C virus

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- Hepatitis C virus (HCV) affects about 3% of the world population (180 million people)
- In Egypt about 15 % of the adult population has HCV antibodies. Active cases between 5-8 millions. With more than new 150K every year.
- It is considered a major cause of chronic liver disease and liver transplantation in Egypt.

Estimated 180 Million individuals infected with HCV worldwide

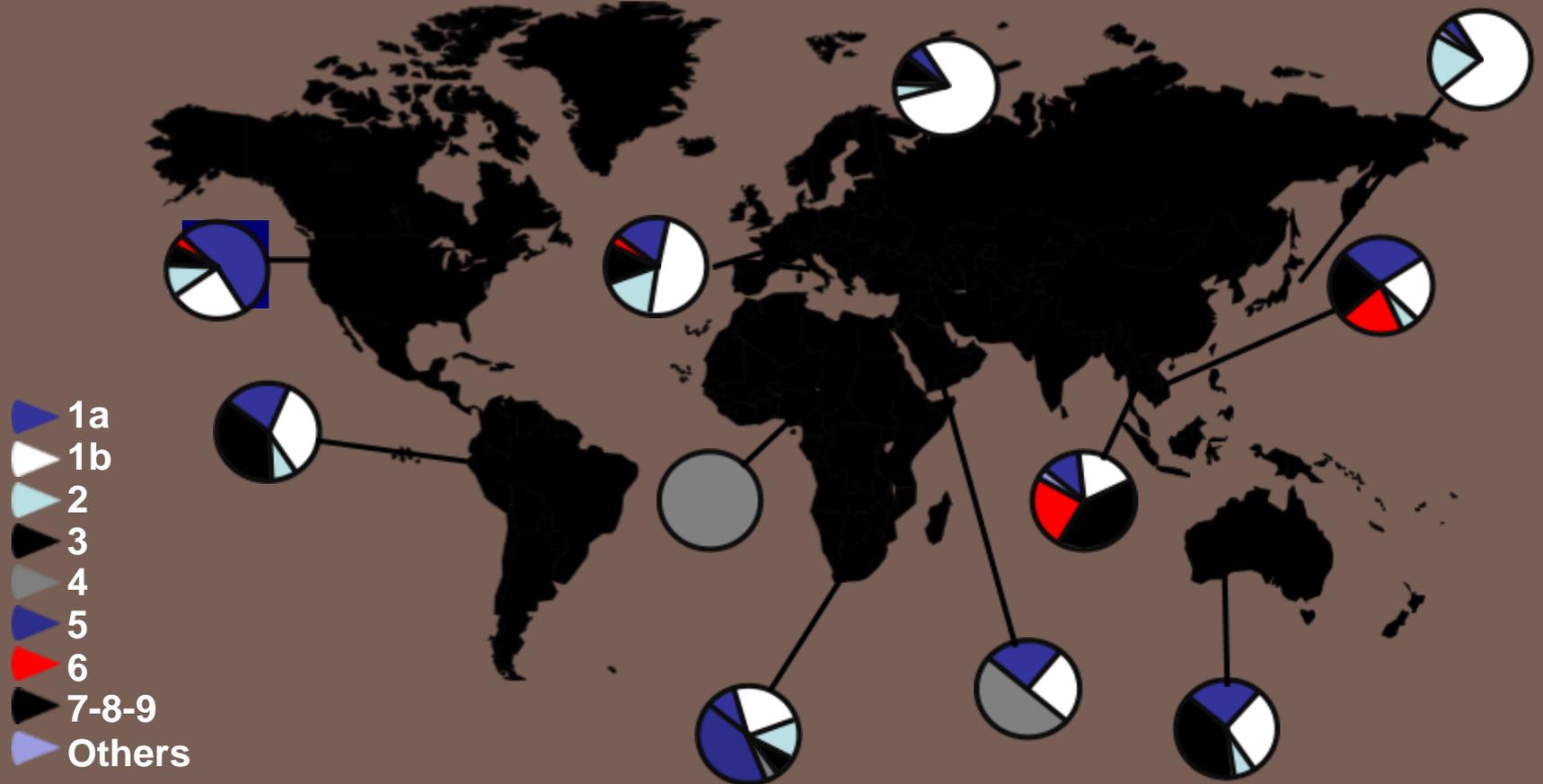


HEPATITIS C VIRUS (HCV)

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- HCV is (50 nm in size), enveloped, single stranded.
- Subdivided into 6 genotypes which have specific geographic distributions.
- The major genotype in Egypt is 4. “Resistant Strain”
- One in five people who become infected may develop cirrhosis without treatment.
- In Egypt, Hepatocellular carcinoma (HCC) is the second most common cancer in men and the 6th most common cancers in women

Worldwide Distribution Of HCV Genotypes



Why is HCV so high in Egypt

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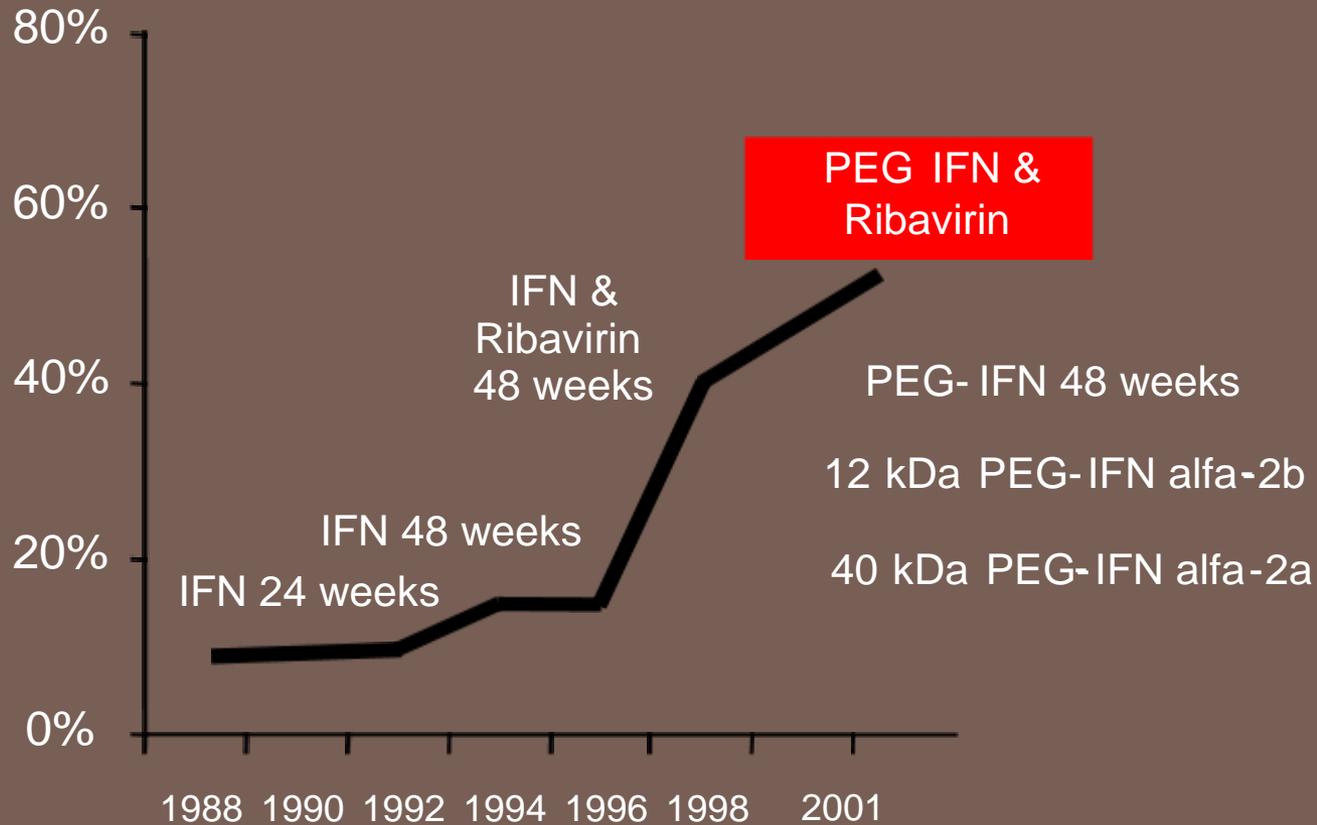
- **The first HCV ELISA tests became available in Egypt in 1992. before that nothing about the occurrence of HCV in Egypt was known.**
- **An Association of HCV with previous parenteral treatment for schistosomiasis.**
- **Egypt's mass campaigns may represent the world's largest iatrogenic transmission of blood-borne pathogens.”**

Lancet 2000; 355: 887–891

- **Since 2000, large number of trials were conducted in Egypt, mainly in National Hepatology and Tropical Medicine Research Institute (NHTMRI, Egypt).**
- **Combined treatment with Pegylated Interferon (PEG-IFN) alfa-2a or alfa-2b and ribavirin (RBV) for 48 weeks succeeded to be the standard therapy for chronic hepatitis C.**

>50% Cure of Chronic Hepatitis C

Sustained virological response



- **PEG-IFN is produced in only two international drug companies . No generics .**
- **The drug original price In Egypt is 9600\$ per patient per course where gross domestic product per capita is 6,600\$ (2012) this leads too limited patient access to the drug.**

Hepatitis C treatment does not fall under the normal definition of post clinical trial access to treatment since its treatment is a limited course for maximum 12 month thus it differs from HIV life time treatment.

- Therefore patients does not need to access the experimental drug after the clinical trial.**

- People who participate in clinical trials are putting their bodies on the line.
- After the finishing of the clinical trail new poor patient fail to reach what consider a stander drug.
- In the beginning the negotiation between the research center and one of the drug company leads to limited number of free drugs for poor patients .
- Limited authority and conflict of interest affect the influence of researcher and research center in negotiation.

- Where is the right of the community for post clinical trial access for the beneficial drug ?
- Low SES was associated with an increased risk of HCV infection and with poor prognosis in HCV infected patients.

*A **community** is a social unit of any size that shares common values; intent, belief, **resources, preferences, needs, risks,** and a number of other conditions may be present and common, affecting the identity of the participants and their degree of cohesiveness.*

- **Even the post clinical trial access of the research subject to beneficial investigation drug is debatable but it is documented in most of the national and international guidelines.**
- **In other hand the right of participants community to access the Investigation drug is not clear.**

Indian Ethical Guidelines

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- **Post trial access to the vaccine should be given first to the community from which the participants were drawn.**

CIOMS 2002

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The committee should obtain assurances from the parties concerned that plans have been agreed for making the investigational intervention **reasonably available in the host country or **community** once its effectiveness and safety have been established.**

CIOMS 2002

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- **Moreover, when the study has external sponsorship, approval should usually be dependent on the sponsors and the health authorities of the host country having **engaged in a process of negotiation** and planning, including justifying the study in regard to local health-care needs.**

- The goal of clinical research is to gain more knowledge as well as health and health care improvement.
- Participants in clinical research contribute in the achievement of this goal. Thus, every effort should be made to assure that participants and their communities are receiving beneficial treatments after trial .

- Different partners in a research study, “investigators, sponsors, communities, national health systems, international organizations” share responsibility for solving this problem.
- Possible ways that will assure that research participants community could have continued access for the treatment should be discussed and settled prior to conduction of the study.
- Sponsors doesn't have the sole responsibility of treating people.

- Since 2008, the Egyptian government has established the National Committee for the Control of Viral Hepatitis as part of the Egyptian National Control Strategy for Viral Hepatitis.

Central Strategies used to reach affordable drug price.

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- Promote Biosimilars medicines including generic substitution.
- Differential pricing .
- Continues Renegotiate about price
- Prioritized patients in different disease stage
- Promote research in new direct anti viral
- Promotion of Hepatitis C epidemiological studies
- Promotion of NGO rules

Win-win Negotiation.

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- **They achieved cooperative goals through an agreement that leads to mutual gain for all parties and their respective sides.**
(patients ,drug companies and state)

Cooperative Achievements

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- Drug companies shared in the structure of treatment centers (23 centers) ,supported training of doctors , awareness campaigns for prevention and treatments and further research .
- State support of the treatment price lead to constant demands of the drugs. Decrease the advertising costs.

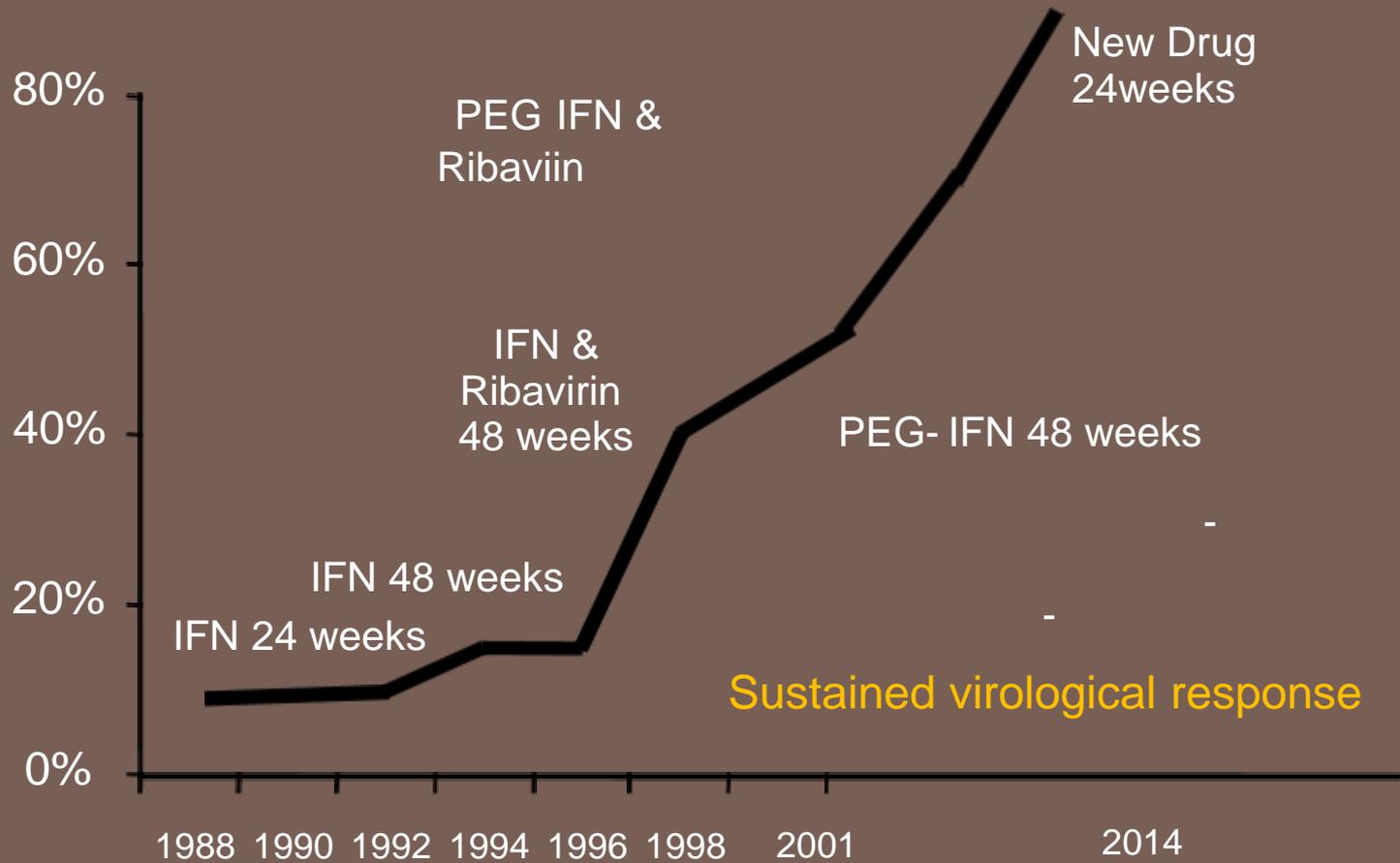
- Renegotiate as a state with both drug companies led to decrease the price of the drug to the Egyptian government to 1 600\$ per patient .
- That led to free treatment for approximately 320K patients within 6 years campaign, out of the estimated 5 million currently in need.
- Last year we treated 42k patient in comparison with just 1 200 in Russia .

New HCV treatment

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- Current treatment of HCV is rapidly evolving. Total duration of treatment and choice of regimen may depend on HCV genotype or subtype and host genotype.
- It is expected that IFN-free regimens will be the future of HCV treatment for the majority of patients

>90 % CURE OF CHRONIC HEPATITIS C ²⁸



In 2012 A New group of direct antivirus

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New negotiation strategy

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- **Early research partnership**
- **Early price negotiation**
- **Differential pricing**
- **Promoting competition for multi-source products.**

In 2013 in the last chance

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- Phase three trial of the new drugs done in Egypt .
With negotiation about national special price.
- New round of negotiation after successful phase three leading to decrease price of the drug course from 90,000 \$ to 2000\$

What do we still need .

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- **Expansion of Affordability and Availability**
- Community partnership . Community Advisory Board (CAB)
- Promotion of national research
- International and National drug policy for essential drugs
- International collaboration . Multi-stakeholder efforts to expand access
- Use of safeguards compatible with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
 - ▣ Friendly law for 'patent opposition'
 - ▣ Compulsory licensing
 - ▣ Biosimilar and generic-agent manufacture

Conclusion:

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- State negotiation was more powerful than research center negotiation and had greater influence on post clinical trial access to medicines .
- **Early** negotiation and research partnership support chance for cheap drugs
- National drug policy is essential
- National ethical guideline support the community rights for post clinical trial drug access

Questions / Comments

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