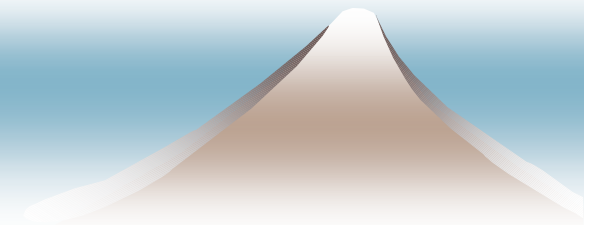


*Will clinical trials for INDs change
the clinical settings in Japan?
The impact of SMOs*

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As A clinician-my standpoint

◆ Workplace

- Internist(rural area)
- Psychiatrist(urban circumstance)
- Industrial psychiatric consultant

◆ Attitude

- Evidence-based practice is vitally important.
- Clinical trials for IND must be evaluated from the view point of EBM.
- Interviewing with certain SMO manager
 - Good feeling to SMO

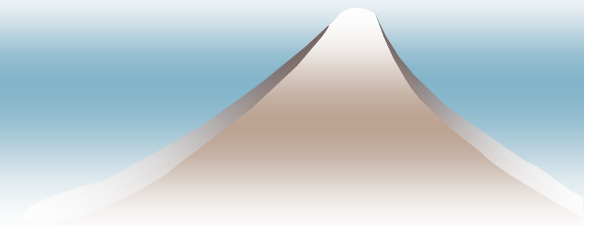
Please refer to my **newest article on SMO.**(“Clinics & Drug Therapy 2003;22(9): 851-6. Elsevier Japan)

Arm against diseases with EBM

- ◆ Effective weapons(drugs)
- ◆ High quality information(EBM)
- ◆ Excellency in clinical expertise

EBM means not performing new clinical trials,
but utilizing existing research evidence.

Those who conceive clinical questions will
surely come across the answers.



PUS and comfortable tension

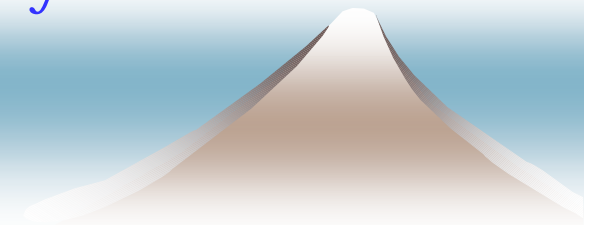
-between professionals and citizen-

- ◆ public understanding of science(PUS)
- ◆ public understanding of medical science(PUMS): Prof. Takaku
- ◆ public understanding of medicine(PUM): Prof. Hashimoto

EBM will make it!

Please refer to my coming article on PUS.

(Molecular Medicine 2003; inprint, Nakayama-shoten)

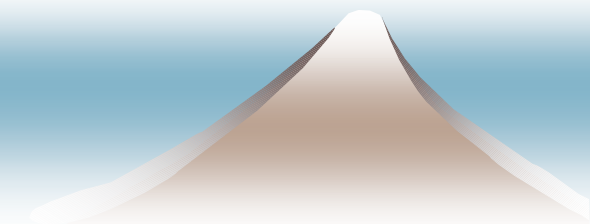


Essential medicine vs. innovative drug

- ◆ Difference toward philosophy of drug usage
- ◆ Food first, medicine next?
- ◆ Not only 3rd world, but also our own country

Medicalization of society

- Compulsive behaviour of chasing “healthy feeling”
- Modern scientific medicine forces people to act as sheep by nature.
- Can doctors can be shepherds?: Not certain.

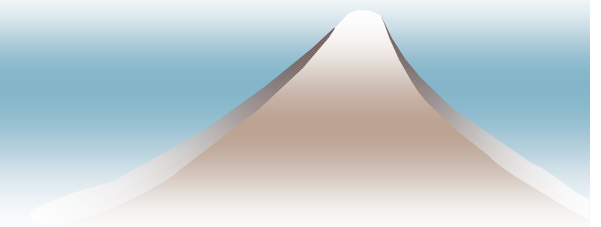


Getting closer to clinical trials

- ◆ SMOs, Doctors initiated IND trials...
- ◆ Feedback from clinical settings.
- ◆ New medical knowledge flows into clinics.
- ◆ Clinical trials mustn't overwhelm clinical practices.

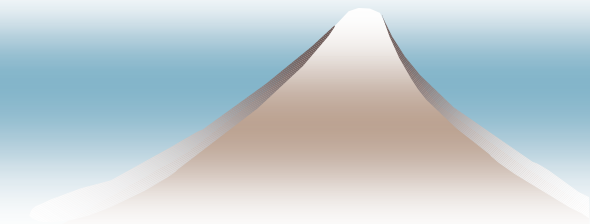
Clinical trials are another way of treatment for patients themselves.

They use trials!



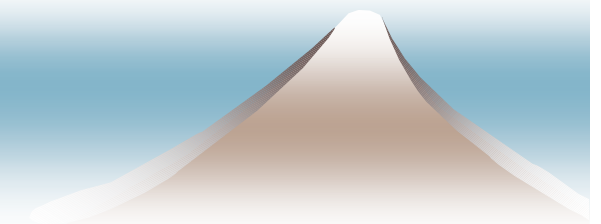
Resourceful Patient

- ◆ Patients are wiser than what we suppose to be.
- ◆ Specialists, generalists, and patients.
- ◆ New style medical professionals.
- ◆ Professionals as good neighbors for patients.
- ◆ I myself ,as a gatekeeper to cutting edge medical technologies.
 - Distance between Tokyo-Gotemba is about 100 km takes 1 hour trip by vehicles.
 - Insufficiency of medical facilities at the east side of Shizuoka prefecture.



Will clinical trials for INDs change my clinical setting in Gotemba?

- ◆ SMOs won't come to Gotemba.
- ◆ IRB/SMO/CRO must be independent each other.
- ◆ Especially of IRB, how to organize people is quite a issue for rather small city as Gotemba.
 - But should not integrate IRB/SMO/CRO at once.
- ◆ Knowledgeable people in rural region should not be ignored.



Summary

- ◆ EBM and PUS reinforce both clinician and citizen.
- ◆ SMOs are a key to improve clinical settings.
- ◆ People are getting wiser and wiser these days.
- ◆ Some obstacles are laying to utilize SMOs for my circumstance.
- ◆ Patients-centred medicine generates patients initiated trials for INDs.

