

# P-one Clinic, Medical Corp. New Volunteer Information

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### I. What are Clinical Trials?

Clinical trials are scientific studies testing the effects of drugs, medical devices or other treatments on humans. Typical trials, sometimes referred to as *clinical studies*, are conducted for the purpose of:

- Measuring the safety and effectiveness of potential drugs, medical devices or other treatments
- Comparing trial-treatments against existing treatments
- Assessing better use of treatments, and how to make them more effective, easier to use, or to decrease side effects
- Identifying how best to use a treatment in a specific population. For example, amongst children or within a particular ethnic group

### II. Research for New Drug Development

Clinical trials for new drug development are instituted over the course of three main stages: Phase I, II and III. Phase I clinical trials are conducted with 50~200 healthy participants and evaluate tolerability and safety, monitor food and drug interaction, as well as gather information about what the drug does to the body, and what the body does to the drug. These factors are observed with incremental dose increases of the investigational drug within a predefined dose range.

Gathering this information is a crucial step in determining the safety of a new drug, how it works, the drug's potential effectiveness as a treatment, and appropriate dosage levels. Phase I trials typically last about 1 year. With successful completion, they then lead to Phase II studies of patients, aiming to further assess drug efficacy, safety, and proper dosage levels. This process can take about 2 years to complete. From there, Phase III studies -- involving a significantly larger number of patients -- are then carried out by a range of general physicians, hospitals and clinics. These studies may take 3 (or more) years to complete. If successful, the trials data is submitted to

the acting regulatory authorities in order to obtain official permission to begin marketing the new drug. Once the review and approval process has been completed by regulatory authorities, the drug can be made available to the general public.

### III. Clinical Trials for Caucasian Volunteers in Japan

In Japan, clinical trials for drug development known as chicken (治験) generally involve Japanese subjects only. However, in certain cases where international drug development requires consideration of multi-ethnic studies in particular, or where pharmaceutical companies are in search of Caucasian Phase II ~ III data from overseas in order to receive drug approval here in Japan, multi-ethnic comparative pharmacokinetics (PK) studies may be instituted. In such cases, studies involving Caucasian volunteers living in Japan are a viable option for sponsoring pharmaceutical companies.

Multi-ethnic comparative PK studies (known as “bridging PK studies”) are typically carried out according to the ‘Phase I’ description provided above. These studies involve participation by Japanese and Caucasians, and/or other ethnic groups, separately observed in a single trial at a single site. Each group is given the same investigational drug at identical doses, with the same diet and same daily routine. By reducing the potential for human variation in technique and judgment, this helps achieve a higher level of comparability through standardization of operating procedures and equipment. Subsequently, this results in higher quality and more robust data for the drug being studied.

### IV. Organizers of Clinical Trials

P-one Clinic in Hachioji (a western Tokyo suburb) is now in the process of growing its Caucasian volunteer group and will manage future trials on-site. Clinical trials are typically commissioned by a sponsoring pharmaceutical company, which outsources its research and development to clinical research specialists such as P-one Clinic, that have the experience, knowledge, staff and facilities to carry out these studies safely and smoothly.

P-one Clinic currently manages a large number of volunteers for clinical trials, with a Japanese database of about 3000 registered members and a growing database of Caucasian volunteers.

### V. Volunteer Safety & Consent

In Japan, as in Western countries, administration of clinical trials is conducted in strict adherence to the legislation provided by government regulatory authorities. Here in Japan, the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceutical and Medical Devices Agency (PMDA) supervise all clinical trials practices. Japanese standards for Good Clinical Practice (called J-GCP or “Japanese GCP”) are based upon International standards for Good Clinical Practice (ICH-GCP), and these standards are strictly applied. An independent review of each trial protocol (which provides a detailed trial plan) is required to be held by a qualified review board. This committee, referred to as an Institutional Review Board (IRB), works together as a team of impartial medical professionals, medical institution representatives and regular citizens, in order to protect the rights, safety and well-being of clinical trial participants. The IRB must review trial protocols and procedures, as well as all supporting materials required to obtain (and document) the informed consent of the clinical trials volunteer (see below).

All trials conducted by P-one Clinic will undergo such a review process before and during the trial, by this qualified Institutional Review Board. All medical staff are highly competent, experienced and professionally trained for the supervision of clinical trials, and facilities are operated in accordance with J-GCP.

When you receive an invitation to participate in a specific clinical study, detailed information will be provided to you regarding the specific purpose of the trial, the investigational drug, time frames, procedures, your rights, compensation, etc. You must receive this complete/comprehensive information about the process before you will be allowed to register to participate in a clinical trial.

\*Side effects of investigational drugs are often a primary concern for prospective volunteers. One important point to note is that all drugs -- including the ones we take for common colds and headaches -- produce side effects. While drugs are administered for the purpose of lessening or stopping the symptoms of a disease or condition, taking a drug produces secondary effects (or any effect other than the intended therapeutic effect). Sometimes, these side effects can be unnoticeable, or include cold-like symptoms, dry throat, stomach cramps or drowsiness, and in rare cases, could include symptoms of a more serious nature. For specific questions about these more serious symptoms, please inquire with one of our bi-lingual doctors during your initial consultation.

\*\*In Japan-based Caucasian studies carried out by P-one, safety data about the drug has been collected already and suitability for trial continuation has been established as a result of prior studies.

## VI. Estimated Schedule for Clinical Trials

Time frames for clinical trials tend to vary in length. Studies carried out at P-one Clinic will typically require a hospital stay of several nights, and in some cases could last up to several weeks. Throughout the course of the study, you will be asked to stay in the hospital, eat the prescribed diet and refrain from any physical overexertion. You will be asked to cooperate for regular blood and urine sampling, temperature, blood pressure and other vital sign checks. Upon your discharge from the hospital, you may then be asked to return for several non-stay/follow-up visits.

## VII. Risks & Benefits of Clinical Trials

As noted in the section on 'Volunteer Safety & Consent' above, strict guidelines are followed throughout the clinical trials process, and experts review the trials to ensure patients are not subjected to undue risk. However, all trials contain some form of risk:

- *there may be unpleasant, serious, or even life-threatening side effects resulting from the treatment.*
- *the treatment may not be effective for the participant.*
- *the protocol may require more of the participant's time and attention than a standard treatment. (Participants may need to visit the study site on a regular basis, be subjected to additional tests, get more treatments than are normally necessary, stay in the hospital and/or follow complex dosage requirements.)*

\*From the FDA's [Basic questions and answers about clinical trials](#)

While healthy volunteers rarely receive any therapeutic benefit from clinical studies, many find clinical trials participation to be a rewarding experience for these and other reasons:

- free comprehensive health check
- gain new knowledge about health/medicine
- financial compensation
- personally satisfying (humanitarian aim, helping to benefit future patients and potentially save more lives.)

## VIII. Volunteer Compensation

Due to the fact that healthy volunteers are unlikely to receive any direct health benefits from participation in the clinical trial, and in order to compensate you for your time and any discomfort experienced during the trials, an honorarium is provided. Compensation provided to volunteers normally varies according to the study, but amounts are based upon the number of hospital visits and the required length of the hospital stay. Volunteers will be provided more specific details about compensation in the informed consent form for each study. For general questions regarding compensation, please [contact us](#) anytime.

## VIX. How to enroll?

To begin taking part in a clinical trial, you will need to become a member of our Caucasian Volunteer Group at P-one Clinic.

Once you complete your registration and initial health check at P-one Clinic, we will be able to match upcoming trial requirements with your profile and then contact you with information regarding studies you may be interested in participating in. If you are interested, we will then invite you to a more detailed trial briefing. At this time, we will explain the purpose, duration, procedures, your rights, any potential risks associated with participation in the trial, compensation, and any further requirements, etc. The briefing will also allow you to consult with P-one Clinic medical staff about any remaining questions or concerns you may have.

As mentioned above, before authorizing your final enrollment for a trial, your 'Informed Consent'<sup>3</sup> is required. This is basically identical to the consent form required of patients who will undertake any serious treatment or medication provided by a doctor. You will be given comprehensive details and information both verbally and in writing. Afterwards, adequate time will be allowed for you to consider the information, consult with those you trust, and to contact us with any remaining questions you may have. Should you wish to continue, you may then sign and return the completed Informed Consent form.

<sup>3</sup> 'Informed Consent' is a legal condition whereby a person can be said to have given consent, based upon a clear appreciation and understanding of the facts, implications and future consequences of their actions -- in this case it is taken as participation in a clinical trial.

This form of documentation is used to verify that you will participate out of your own free will, and with full understanding about the nature and implications of your participation. Please note that you may withdraw from a trial at anytime without explanation -- even once you have given Informed Consent.

Once your Informed Consent is received you will be given a medical check, followed by an interview to confirm that you are in good health and that you meet the requirements to participate.

## X. Enrollment Restrictions

Clinical trials have certain restrictions which may or may not prevent you from participating, and these tend to vary by trial. Please consider these restrictions when applying to become a volunteer:

- Insufficient break between participation in recent clinical trials: Usually, a 4-month time lapse between periods of participation is required.

- Participation in more than one trial for the same drug: This is **not** allowed, regardless of time frame between trials.
- Recreational drug use (marijuana etc.): Recreational drug users will not be allowed to participate in clinical trials.
- Smoking: There are many cases where smokers are refused participation or may be asked to refrain completely while participating in the trial. If you are a smoker please keep this in mind.
- In the days leading up to your trial, you may also be asked to avoid consuming products containing caffeine, alcohol and grapefruit, as these substances can significantly alter drug action and absorption, and negatively affect the clinical trial results.
- While a working visa is not a requirement for participation please note that tourist visa holders will not be considered for participation at this time.
- Follow-up checks or interviews may be required after completion of the primary clinical trial. Therefore participants selected for the trial should intend to remain in Japan for at least several months from the completion of the trial.

#### XI. About Observation Procedures/Hospital Stay

- Bring your Alien Registration Card and passport when you visit the hospital for the medical check and admission into the clinical trial. A photocopy will be kept on file at P-one.
- During your stay, the hospital will provide all volunteers with towels, pajamas, soap, toothbrush and toothpaste, shampoo and conditioner, disposable razors and slippers.
- Please bring sufficient underwear and any other personal items, as needed. Laundry service will be provided.
- We suggest you bring books, games and other items to help pass time during the trial. A television is available in the volunteer lounge and internet (cable modem) hook-ups will be available for those with laptop/notebook computers.
- Please refrain from bringing outside food/drinks to the hospital during the trial. All meals will be taken according to a study plan and any variation from this is likely to negatively impact the study.

#### XII. Find Out More

- [Wikipedia](#)
- [US National Institutes of Health](#)
- [US Food and Drug Administration](#)

#### Contact P-one Clinic Medical Corp.

Please contact us today to discuss the opportunity for participation in future clinical trials. We look forward to hearing from you with any further questions, comments or concerns.

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