wherein participants in a clinical trial use their own internet-enabled devices to provide study data.

Unless the digital devices have been set up to run in kiosk mode it may be impossible to prevent users from modifying the device's time and date. This is especially true with BYOD trials, wherein the party responsible for collecting the clinical trial data or setting up the digital devices for the trial or providing a dedicated application to be used in the trial may not be given rights to access the device's clock (by the user). Moreover, it might even be not permissible to control the device's clock by a party organizing the clinical trial. Yet, it is important to record observations of the user right on time. The users may not always remember or bother to punctually record notes, such as time of taking medication and generally answers to predefined questions or free text. If they can freely alter the time and date of their devices, it may be possible to falsely record observations as if they were timely entered.

It is desirable to track and validate the time of the devices.

SUMMARY

According to a first example aspect of the invention there is provided an automatic time tracking and validating method of a portable digital device, including: maintaining, by the portable digital device, a current clock time and current uptime, wherein the portable digital device includes: a user interface; a device communication interface; and device software stored in device memory and operable to be loaded into and executed by a device processor; recording, by the portable digital device, one or more first entries, each of the one or more first entries including: user information; the current clock time; and the current uptime; performing a reference time recording process one or more times, including: recording, by the portable digital device, one or more second entries, each of the one or more second entries including: the reference time, wherein the reference time is kept by a server; the current clock time; and the

current uptime; and providing, by the portable digital device, the server with the one or more first entries and the one or more second entries, wherein the server includes: a server communication interface; and server software stored in server memory and operable to be loaded into and executed by a server processor.

The method may further comprise using encryption by the portable digital device such that access of persons to the first and second entries is inhibited and integrity of the first and second entries is protected.

The automatic time tracking and validating method may enable tracking and validating times recorded for user information without exposing potentially sensitive information, e.g. to human beings. The automatic time tracking and validating method may enable tracking and validating times recorded for user information without necessarily having continuous online access.

The recording of the first entry may be performed in response to the portable digital device receiving from a user the user information.

The user information may comprise information provided by the user. The user information may comprise information describing the physical state of the user. The user information may comprise information describing the mental state of the user. The user information may be measured from the user. The user information may comprise clinical outcomes. The clinical outcomes may be patient reported. The clinical outcomes may be reported by a clinician. The clinical outcomes may be reported by an observer. The clinical outcomes may comprise measurements, e.g. blood glucose measurements. The user information may include data concerning one or more performances of the user, e.g. results of a hand tremor status.

The user information of each first record may be freely defined by the user, optionally comprising one or more choices made from respective groups of predetermined alternatives.

The user may be allowed to record input such as observations when preferred by the user. The method may enable time stamping the user information and verifying reliability of the time stamping with and without network access.

The method may further comprise verifying reliability of the recorded current clock times of the first entries. The verifying may be performed using the second entries.

The method may enable verifying the reliability of the recorded current clock times solely based on the information available to the portable digital device without access to the server. Additionally, the method may enable verifying the reliability of the recorded current clock times using the information available to the server.

The verifying may be performed by the server. Alternatively or additionally, the verifying may be performed by the portable digital device.

The recording of the first and second entries may be performed by a time tracking module of the portable digital device. The communicating with the server may be performed by the time tracking module. The obtaining of the current reference time from the server may be performed by the time tracking module. The using of the encryption may be performed by the time tracking module.

The second entries may be recorded in the portable digital device. Alternatively, the second entries may be recorded to the server by providing the current clock time and uptime. The server may record the reference time on recording the second entry. The server may provide the portable digital device with the reference time.

The method may enable maintaining reference time records by the server for comparison with the first entries recorded at the portable digital device.

The method may further comprise maintaining a boot number counter by the portable digital device or by the time tracking module. The method may further comprise continually checking if the boot number counter value has increased and if yes, responsively performing the reference time recording process. The boot number counter value may be additionally recorded to next first entry. The boot number counter value may be additionally recorded to the second entry on performing the reference time recording process responsive to the increasing of the boot number counter value.

The method may further comprise determining whether the boot number counter value has increased by more than one since previously recorded combination of boot number counter value, uptime and current clock time. If yes, the method may comprise recording a first indication to a subsequently recorded first entry. The first indication may indicate unreliability of the clock time until next performing of the reference time recording process.

The use of the boot number counter may enable checking whether it is still possible to track backwards the correct time for each recorded entry based on the uptime.

The method may further comprise determining whether the portable digital device has been restarted once after recording both the previous first and second entries and if yes, recording next first entry with a third indication. The third indication may indicate one restart since recording previous first and second entries.

The method may comprise determining, from the recorded current uptime and the reference time of the second entries, if the portable digital device has been restarted and if yes, subtracting the uptime from the current clock time and recording the result as previous starting time.

The method may further comprise determining whether the previous starting time calculated for one first entry is later than that calculated for a subsequent first entry

and if yes, determining that at least one of these first entries is erroneous. The method may further comprise determining, based on the reference time whether the subsequent first entry had a correct clock time and if yes, then determining the one first entry and the subsequent first entry respectively as erroneously and correctly timed.

The method may enable determining the presence of impossible sequences of time stamps as indication of errors in the time stamping.

The method may comprise compensating time zone changes by detecting abrupt changes in the difference between the recorded current clock time and either the uptime or reference time, when the difference is N times half an hour, wherein N is an integer between -47 and -1 or +1 and +47.

The verifying may comprise determining, for one uptime period, a difference between the recorded current uptime and the current clock time of the second entries and checking whether that difference has changed more than a predetermined first maximum change. The uptime period may refer to the period from starting up (e.g., cold boot, warm boot, power on) until a next shutdown or restart of the portable digital device. The first maximum change may be greater than 10 s, 30 s, 1 min, 2 min, 5 min or 10 min. The first maximum change may be per 24 hours greater than 10 s, 30 s, 1 min, 2 min, 5 min or 10 min.

The verifying may comprise determining, for one uptime period, a difference between the recorded current uptime and the current clock time of the first entries and checking whether that difference has changed more than a predetermined second maximum change. The second maximum change may be greater than 10 s, 30 s, 1 min, 2 min, 5 min or 10 min

The method may comprise determining which ones if any of the first entries the recorded current uptime and current clock time mutually change more than by second

maximum change and recording to such first entries a second indication. The second indication may indicate unreliable current clock time.

The using encryption by the portable digital device may comprise encrypting the first entries. The using encryption by the portable digital device may comprise encrypting the second entries. The using encryption by the portable digital device may comprise cryptographically signing the first entries. The using encryption by the portable digital device may comprise cryptographically signing the second entries. The encryption may employ asymmetric encryption. The encryption may employ public key encryption. The encryption may employ symmetric encryption.

The second entry may comprise user information. The second entry may be one of the first entries. The recording of the user information in some second entries or having the second entry as one of the first entries may remove the need of recording separate first and second entries.

The second entry may be recorded one or more times before first time of recording the first entry.

According to a second example aspect of the invention there is provided a portable digital device including: at least one circuitry configured to maintain a current clock time and a current uptime; at least one processor configured to perform with the at least one circuitry at least the method of the first example aspect.

The at least one processor may be further configured to cause providing the server with the first and second entries.

The at least one processor may be further configured to use encryption such that access to content of the first and second entries is inhibited and integrity of the first and second entries is protected.

According to a third example aspect of the invention there is provided a computer program including computer executable program code which when executed by at least one processor causes an apparatus at least to perform the method of the first example aspect.

The computer program may be protected against reverse engineering. The computer program may be code obfuscated. The computer program may be configured to decrypt and sandbox the computer program code for run time.

According to a fourth example aspect of the invention there is provided a computer program product including a non-transitory computer readable medium having the computer program of the third example aspect stored thereon.

Any foregoing memory medium may comprise a digital data storage such as a data disc or diskette, optical storage, magnetic storage, holographic storage, opto-magnetic storage, phase-change memory, resistive random access memory, magnetic random access memory, solid-electrolyte memory, ferroelectric random access memory, organic memory or polymer memory. The memory medium may be formed into a device without other substantial functions than storing memory or it may be formed as part of a device with other functions, including but not limited to a memory of a computer, a chip set, and a sub assembly of a digital device.

Different non-binding example aspects and embodiments of the present invention have been illustrated in the foregoing. The embodiments in the foregoing are used merely to explain selected aspects or steps that may be utilized in implementations of the present

Claims

1. An automatic time tracking and validating method of a portable digital device, comprising:

maintaining, by the portable digital device, a current clock time and current uptime, wherein the portable digital device comprises:

a user interface;

a device communication interface; and

device software stored in device memory and operable to be loaded into and executed by a device processor;

recording, by the portable digital device, one or more first entries, each of the one or more first entries comprising:

user information;

the current clock time; and

the current uptime;

performing a reference time recording process one or more times, comprising:

recording, by the portable digital device, one or more second entries, each of the one or more second entries comprising:

the reference time, wherein the reference time is kept by a server;

the current clock time; and

the current uptime; and

providing, by the portable digital device, the server with the one or more first entries and the one or more second entries, wherein the server comprises:

a server communication interface; and

server software stored in server memory and operable to be loaded into and executed by a server processor.

2. The method of claim 1, wherein the recording of the one or more first entries is performed in response to the portable digital device receiving, from a user, the user information.

3. The method of claim 1, wherein the user information comprises information provided by a user.

4. The method of claim 1, further comprising:

verifying reliability of the current clock time of the one or more first entries.

5. The method of claim 1, further comprising:

using encryption by the portable digital device, wherein access to the one or more first entries and the one or more second entries is inhibited, and wherein integrity of the one or more first entries and the one or more second entries is protected.

6. The method of claim 1, wherein the user information is measured from a user.

7. The method of claim 1, wherein the user information is defined by a user.

8. The method of claim 1, wherein a user is allowed to record input when preferred by the user.

9. The method of claim 4, wherein the verifying is performed using the one or more second entries.

10. The method of claim 4, wherein the verifying is performed by the server.

11. The method of claim 1, wherein the recording of the one or more first entries and the recording of the one or more second entries are performed by a time tracking module of the portable digital device.

12. The method claim 11, further comprising:

obtaining the reference time from the server, wherein the obtaining is performed by the time tracking module.

13. The method of claim 1, wherein the server provides the portable digital device with the reference time.

14. The method of claim 11, further comprising:

maintaining a boot number counter by the portable digital device or by the time tracking module.

15. The method of claim 14, further comprising:

checking if a value of the boot number counter has increased and if yes, responsively performing the reference time recording process.

16. The method of claim 15, wherein the value of the boot number counter is recorded to a next first entry.

17. The method of claim 16, wherein the value of the boot number counter is recorded to the one or more second entries on performing the reference time recording process responsive to the increasing of the value of the boot number counter.

18. The method of claim 17, further comprising:

determining whether the value of the boot number counter has increased by more than one since the recording of the value of the boot number counter, the current uptime, and the current clock time.

19. The method of claim 18, further comprising:

recording a first indication to the next first entry if the value of the boot number counter has increased by more than one since the recording of the value of the boot number counter value, the current uptime, and the current clock time.

20. The method of claim 19, wherein the first indication indicates unreliability of the current clock time until a next second entry is recorded in the reference time recording process.

21. The method of claim 20, further comprising:

determining, from the current uptime and the reference time of the one or more second entries, if the portable digital device has been restarted and if yes, subtracting the current uptime from the current clock time to yield an amount and recording the amount as a previous starting time.

22. The method of claim 21, further comprising:

determining whether the previous starting time calculated for one first entry is later than that calculated for a subsequent first entry and if yes, determining that at least one of the one or more first entries is erroneous.

23. The method of claim 22, further comprising:

determining how much the previous starting time calculated for one first entry differs from that calculated for one second entry, and based on the difference, determining: (i) the one first entry as having correct current clock time and therefore the one first entry being correct, (ii) the one first entry being erroneous, or (iii) that it is not possible to determine whether the one first entry is correct or erroneous.

24. The method of claim 23, further comprising:

determining, based on the reference time whether the current clock time of the one first entry is correct, and if yes, determining the one first entry and the subsequent first entry respectively as erroneously and correctly timed.

25. The method of claim 24, further comprising:

compensating time zone changes by detecting abrupt changes in the difference between the current clock time and either the current uptime or the reference time, when the difference is N times half an hour, wherein N is an integer.

26. The method of claim 4, wherein the verifying comprises determining, for an uptime period, a difference between the current uptime and the current clock time of the one or more

second entries and checking whether that difference has changed more than a predetermined first maximum change.

27. The method of claim 4, wherein the verifying comprises determining, for an uptime period, a difference between the current uptime and the current clock time of the one or more first entries and checking whether that difference has changed more than a predetermined second maximum change.

28. The method of claim 25, further comprising:

determining, for any of the one or more first entries, the current uptime and current clock time mutually change by more than the predetermined second maximum change and recording to such first entries a second indication.

29. The method of claim 28, further comprising:

determining whether the portable digital device has been restarted once after recording at least one of the one or more first entries and at least one of the one or more second entries, and if yes, recording another first entry with a third indication.

30. The method of claim 1, wherein the one or more second entries comprise the user information.

31. The method of claim 1, wherein at least one of the one or more second entries is at least one of the one or more first entries.

32. A portable digital device, comprising:

at least one circuitry configured to maintain a current clock time and a current uptime;

at least one processor configured to perform with the at least one circuitry at least the method of claim 1.

33. A computer program comprising computer executable program code, which when executed by at least one processor, causes an apparatus at least to perform the method of claim 1.

34. A computer program product, comprising:

a non-transitory computer readable medium having the computer program of claim 33.