ALLEGATO 1 VERBALE 3

1. Cosa si intende per Visita di Inizio Studio e quali attività vengono svolte durante la stessa

   Sommare i valori 2 celle Excell

   "No clinical studies that assess the reproductive and developmental toxicity of emactuzumab as a single agent, in combination with atezolizumab, or in combination with selicrelumab have been conducted to date"

2. Cosa si intende per Visita di Chiusura studio e qualia attività vengono svolte durante la stessa

   Dividere i valori di 2 celle Excell

   "Immunoglobulins may cross the placenta. Therefore, emactuzumab is expected to cross the placenta and may cause harm to the fetus. Therefore emactuzumab should not be administered to pregnant women"

3. Cosa si intende per visita di Monitoraggio e qualia attività vengono svolte durante la stessa

   Moltiplicare i valori di 2 celle Excell

   "Women of childbearing potential should take necessary precautions to avoid pregnancy while receiving emactuzumab treatment and to use effective contraceptive methods that result in a failure rate of ≤ 1% per year throughout the treatment period and for 7 months after discontinuation of treatment"

4. Cosa si intende per Audit, chi lo conduce e quali attività vengono svolte durante la stesso

   Sottrarre i valori di 2 celle Excell

   "It is not known whether emactuzumab, as a single agent or in combination with atezolizumab or selicrelumab, is excreted in human milk. However, IgG is generally known to be excreted in breast milk, so emactuzumab must not be administered to nursing mothers"

5. Cosa è un sistema IWRS

   Impostare una sommatoria di valori di 2 celle Excell

   "The recommended dose for adults and adolescents 12 years of age and older is 480 mg nivolumab and 160 mg relatlimab every 4 weeks administered as an intravenous infusion over 30 minutes. This dose is established for adolescent patients weighing at least 30 kg "

6. Cosa si intende per studio sponsorizzato in doppio cieco controllato

   Filtrare un elenco Excell

"Shipping documents are an essential part of the IP supply records. They should be verified, signed, and dated by the designated person receiving the IP shipment and filed in the Pharmacy Binder together with the IRT confirmations (e-mail)"

7. Cosa si intende per IMPS e terapie di Background

   Impostare un filtro su un elenco Excell

   "For the monitoring temperature process during storage at sites, Sites can use their own logs provided all essential information reported in the temperature log template is available in the site temperature log template (i.e. date, min/max temperature, initials of site staff performing the temperature check).The site will be informed if any action should be taken after this review"

8. Cosa sono le Good Clinica Practice

   Calcolare una media tra più valori di celle Excell

   "Only patients enrolled in the study may receive IP, in accordance with all applicable regulatory requirements. All IPs must be stored in a secure area with access limited to the authorized site staff and under physical conditions that are consistent with IP-specific requirements"

9. Cosa è una CRO e quali funzioni svolge

   Aggiungere un collegamento ipertestuale in una cella Excell

   "Any missed drug dose should be reported by the patient in the patient diary. If vomiting occurs, no additional capsule should be taken that day in an effort to replace the drug that has been vomited. Patients should be instructed to drink an adequate amount of water daily"

10. Cosa si intende per Sponsor e quali funzioni svolge

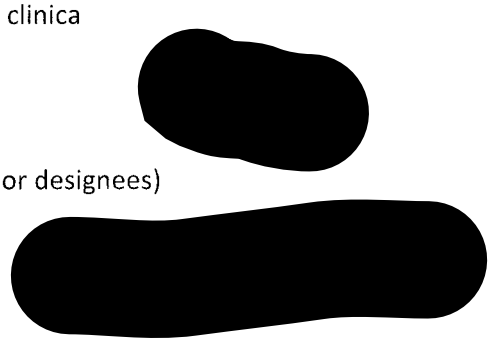
    Impostare una cella Excell in formato data ora gg/mm/aaaa hh:mm

    "IP destruction/disposal will be documented by site personnel on the Site/Master IP Accountability Log, available in the Pharmacy Binder, and will be verified by the Clinical Research Associates (or designees)"

11. Chi è il CRA e quali funzioni svolge nell'ambito di una sperimentazione clinica

    Giustificare un testo in una cella Excell

    "IP may only be destroyed on site by the Clinical Research Associates (or designees)



or site personnel if previously approved by Sponsor and as dictated by local regulations on hazardous medical waste disposal.If local country regulations require, sites with approved destruction SOPs will be allowed to destroy the IP"

12. Come è definibile il braccio di controllo di uno studio clinico

    Definire il bordo di una cella Excell

    Study drugs capsules should not be opened, cut, crushed and/or manipulated. Exposure to crushed or opened capsules should be avoided. If prior to study drugs accountability any sign of cutting, crushing or manipulating is evident on returned capsules, counting should be performed in safe conditions.

13. Cosa si intende per "PLACEBO"

    Impostare il carattere Symbol in una cella Excell

    Dispensing errors of any kind should be thoroughly documented in the subject's medical records. Used and/or partially used IP should be stored in a box at room temperature for IP accountability.

14. Cosa è un Pharmacy Binder e cosa contiene

    Filtrare un elenco Excell per colore

    "A patient will be considered sufficiently compliant with study treatment if he/she has taken at least 80% of the prescribed dose over the total duration of study drug dosing.

15. Cosa si intende per Selection Visit e quali attività vengono svolte durante la stessa

    Impostare un filtro di ricerca superiore ad un valore in un elenco Excell

    "When compliance is less than 80% for a single study visit, the Investigator should review instructions with the patient to correctly take the assigned dose of study drug"

16. Quali sono le figure professionali coinvolte nello svolgimento di uno studio Clinico

    Impostare un filtro di ricerca minore ad un valore in un elenco Excell

    " When compliance is less than 80% for two subsequent study visits, the Investigator can consider withdrawing the patient from study, after a discussion with the medical team of the Sponsor and/or its designee(s), however the final"

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decision remains with the Investigator or its authorized designee(s) only"