

ALLEGATO n. 3 - VERBALE N. 5

TESTO 1

Quesiti:

- Descrivere uno studio osservazionale.
- Come viene definito il garante della privacy?
- Indicare qual è la procedura corretta per inserire simboli speciali non presenti sulla tastiera.
- Leggere e tradurre il seguente testo:

"For this reason, clinical evaluation is not recommended to make treatment decision after neoadjuvant or adjuvant chemoradiotherapy for rectal cancer, but surgical reconnaissance is at least considered to exclude local recurrence or relapse of disease, nevertheless considering that surgery is still the primary treatment modality for rectal cancer."

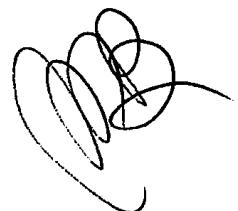
A handwritten signature consisting of several loops and a stylized initial, possibly 'M' or 'S'.

TESTO 2

Quesiti:

- Cosa si intende per Good Clinical Practice (GCP)?
- Cos'è il consenso informato?
- Cosa permette di visualizzare la modalità Relatore nel programma Power Point?
- Leggere e tradurre il seguente testo:

"The purpose of this study was to evaluate the role played by tumor regression grading on the evaluation of pathological response to chemoradiotherapy, compared with both the predicting value of the clinical response to neoadjuvant therapy and pathologic response evaluation."




TESTO 3

Quesiti:

- Quali sono le funzioni del Comitato Etico Indipendente?
- Quando una reazione avversa (AE) viene definita grave (SAE)?
- Qual è il percorso corretto per visualizzare l'anteprima di stampa di un documento Word?
- Leggere e tradurre il seguente testo:

“The object of neoadjuvant chemoradiotherapy regimens is a downstaging or downsizing of advanced rectal tumor to increase the rate of curative resection and reduce loco-regional failure. A reliable method of assessing response to adjuvant therapies is required to help standardize the assessments of new multimodality therapies.”



TESTO 4

Quesiti:

- Indicare alcune funzioni del PI (Principal Investigator).
- Cos'è una Biobanca?
- Indicare qual è la procedura corretta per inserire una tabella in un file Excel.
- Leggere e tradurre il seguente testo:

"Patients who had no detectable tumor present on clinical evaluation were categorized as clinical complete responders. Partial response was defined in patients who had a 50% reduction of the major dimension of the tumor."

A handwritten signature consisting of two stylized, overlapping loops at the top and a cursive word "Pisa" below them.

TESTO 5

Quesiti:

- Cosa si intende per studio clinico progettato in cieco e doppio cieco?
- Quali sono le funzioni del Responsabile della protezione dei dati (RPD)?
- Come viene definito un paragrafo nel programma Word?
- Leggere e tradurre il seguente testo:

“Our results lead us to consider only pathologic evaluation to determine the response to neoadjuvant treatment: the application of tumor regression grading on the specimens obtained after combined neoadjuvant chemoradiotherapy and surgery is useful to plan a better therapeutic strategy on the ground of a quantitative evaluation of the response to neoadjuvant treatment”

A handwritten signature consisting of a stylized heart shape above the word "delle".

TESTO 6

Quesiti:

1. In un database di uno studio clinico a cosa corrisponde ogni riga?
2. Indicare alcuni principi delle Good Clinical Practice (GCP).
3. Per inserire una formula in una cella Excel cosa devo fare?
4. Leggere e tradurre il seguente testo:

“From 1994 to 2003, 58 patients with a primary diagnosis of rectal cancer were studied at our department and enrolled in a single center, not randomized study based on 5-week sessions of radiotherapy associated with chemotherapy infusion, followed by surgical resection.”

A handwritten signature in black ink, appearing to read "M. P. Galle".

TESTO 7

Quesiti:

- Cosa si intende per studio di coorte?
- Cosa si intende per dati sensibili?
- Con il programma Power Point è possibile stampare più di una diapositiva per foglio?
- Leggere e tradurre il seguente testo:

“The goal of neoadjuvant chemoradiotherapy should be the complete regression of tumor: the effect of radiation on rectal wall, lymph nodes, fatty perirectal tissue, and their relationship with neoplastic growth is the object of restaging because all of them work together to make the response to chemoradiotherapy.”

A handwritten signature consisting of two stylized, cursive loops on top and a more fluid, horizontal line with a flourish at the bottom right.

TESTO 8

Quesiti:

- In cosa consiste la randomizzazione?
- Descrivere uno studio di fase 3
- Quale comando da tastiera si usa per spostarsi da una cella all'altra di una tabella?
- Leggere e tradurre il seguente testo:

"All procedures included in the protocol were analyzed and approved by an ethical committee. All patients were informed by a surgeon and a radiotherapist involved in the study about all the procedures and foreseeable side effects of the protocol and the aim of the study. We obtained a signed informed consent from all patients."

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TESTO 9

Quesiti:

- Quali sono le fasi di uno studio clinico?
- Cos'è la Dichiarazione di Helsinki?
- A cosa serve una tabella pivot nel programma Excel?
- Leggere e tradurre il seguente testo:

“Pathologic response resulted to be associated with regression grade, this results could be quite obvious because regression grade is a pathologic feature that evaluates the response to chemoradiotherapy; it is noteworthy on the other hand that regression grade is a quantitative and comparable pathological feature”

A handwritten signature in black ink, appearing to read "MB" above a stylized "f".