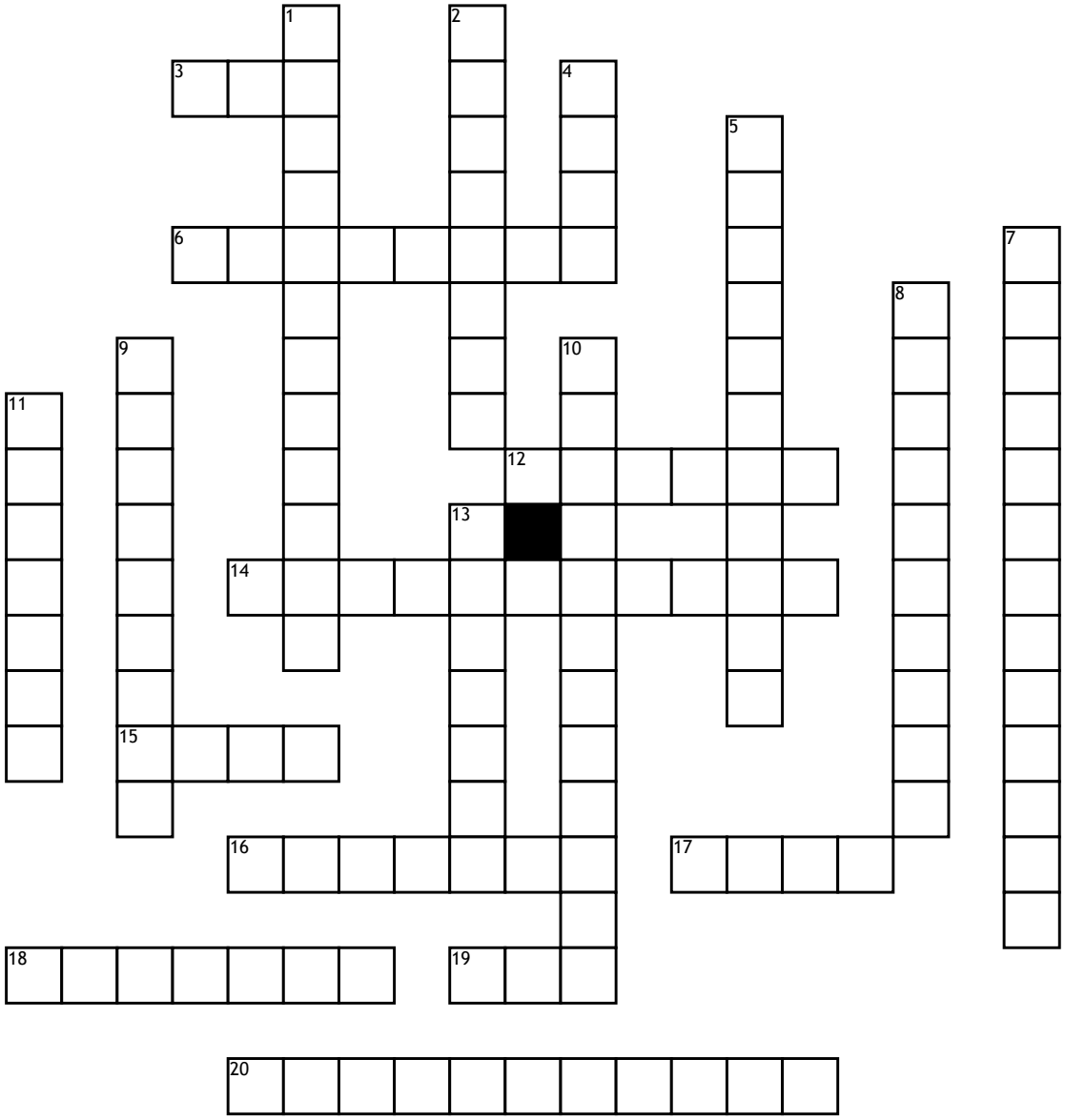
Name: _____ Date: _____

CRCR130 Crossword



Across

3. Regulates, evaluates and monitors the safety, efficacy, and quality of therapeutic and diagnostic products in Canada

6. Investigator related inspection

12. International set of standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials

14. An REB must be this

15. Canadian regulator branch responsible for inspections

16. An Ethics board can be local or _____

17. System to collect and analyze information, identify and investigate problems, and take appropriate and effective action to prevent their recurrence

18. Informed Consent is a _____ of information exchange

19. US equivalent of CTA

20. A deficiency or deviation from Division 5 noted by the inspector

Down

1. Any negative occurrence in the health of a clinical trial subject who is administered a drug

2. The study includes a sufficient number of patients with the disease or condition being studied

4. Pharmacokinetic studies

5. Do no harm

7. For informed consent to be valid the subject has to show ___

8. The act by a regulatory authority(ies), of conducting an official review of documents, facilities, records

9. To be meaningful and informed consent must be ___

10. Clinical study lacking a comparator

11. Informed consent consists of initial and _____ consent

13. Initiates a clinical trial