



The Royal College of Pathologists

Pathology: the science behind the cure

Outline of licensing arrangements with commercial companies

Background

The College is willing to enter into a licensing agreement, with companies whose systems meet the minimum requirements outlined in College guidance entitled *Minimum requirements for computerised cancer histopathology reporting, data recording and downloading to cancer registries* (<http://www.rcpath.org/index.asp?PageID=262>).

The College charges a fee for awarding a licence the costs of which are available on application to the chief Executive.

What do companies receive when entering into a licensing agreement with the College?

1. Initial encouragement from College to provide software that meets the reporting and information management needs of UK laboratories.
2. Limited facilitation (Q&A on what needs to be done to achieve licensing) during the pre-licensing phase.
3. College guidance entitled *Minimum requirements for computerised cancer histopathology reporting, data recording and downloading to cancer registries*.
4. Use of College trademark. The trademark may only be used in association with the software product detailed in the licence agreement and comply with the agreement.
5. Advance notification of new datasets and planned changes to existing datasets.
6. Permission to incorporate datasets and dataset of guidelines into software.

The licence

- a. One licence per 'site' (one site is a single hospital or laboratory or a group of laboratories sharing a single networked pathology reporter database – Working Group on Cancer Services, 27 January 2004).
- b. A licence will be granted to companies for a specific product that meets the College's minimum requirements described in *Minimum requirements for computerised cancer histopathology reporting, data recording and downloading to cancer registries*.
- c. If a company expects substantial variations in the way the product is implemented in different laboratories e.g. if each laboratory has to design its own dataset system using software tools provided by the company, then the company has to satisfy the College that its arrangements for controlling this process will ensure that the College's minimum requirements are met. The College would not expect to licence the unique product of each laboratory.
- d. To be awarded a licence, the company must demonstrate compliance with the minimum standards and demonstrate a working version of at least one dataset.
- e. Once a licence has been awarded, College involvement with the development of a specific product will be minimal and confined to clarification of technical aspects of the work. Companies are encouraged to work with prospective customers to refine their products.
- f. A company wishing to suggest changes to the terminology of core data items or clarification of pathological terms should address their suggestions to the Chairman of the Working Group on Cancer Services. If, after discussion with the authors, such changes are deemed to be appropriate then the dataset may be amended. The resulting changes will be available to all.

- g. Additional data items may be provided to meet local clinical requirements. The College does not wish to control this facility. Companies should provide the College with lists of additional data items requested by users; these will be passed on to the authors for consideration when revising the datasets.
- h. Where possible, users should discuss the nature of additional dataset items with the appropriate specialist pathology groups so that consistent definitions of the data items can be agreed for use in different sites. This will allow retrospective aggregation of data if new data items become part of the core dataset. E.g., data items required for clinical trials and a consistent rule base to determine the % cells labelled needed to define positivity for a particular immunocytochemical marker.
- i. Each quarter the College will request that the company submit a list of sites implementing their system.

Monitoring

The College will send a letter, after the first year, to the users asking them if the companies have delivered the product to their specification. If response is yes, no follow up is required. If the response is no, further follow will be initiated after 6 months.

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