

The Pathologist's Role in the Diagnosis and Management of Disease

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ACM Global Central Laboratory is a central laboratory for pathology and microbiology clinical trial studies, in addition to chemistry and hematology studies. In the clinical trial arena, pathology plays a critical role when tissue specimens are an essential component for the diagnosis and for assessing response to treatment, especially in oncology studies.

In many cases, the central laboratory provides the confirmation of diagnosis for valid inclusion of the subject in a trial. Studies involving tissue pathology require accurate and standardized interpretations of specimens from similar areas and are essential for the assessment of primary end points prior to submission of the test product for approval to the FDA. Some studies require a primary interpretation by one pathologist and a blinded secondary interpretation by a second pathologist, with the provision of a final adjudication read by a third pathologist when there is discord between the first and second interpretations. ACM Global Central Laboratory is uniquely set up with a large pathologists staff who are able to provide all three independent readings in a single facility.

The key elements for a successful study involving pathology tissue are: First, standardized reporting from blinded skilled anatomic pathologists, which allows for ease of study assessments at data lock. Second, specimen control throughout the evaluation allows for not only a financial saving related to the shipping of slides or blocks from laboratory to laboratory, but also ensures the specimen is stored and returned to the sponsor or original facility. Third, the key role of the experienced pathologist in evaluating critical complex criteria for the diagnosis, treatment or management of a disease, whether utilizing experience and exposure derived from cases in the acute hospital/outpatient environment translating to the clinical trial space.

The following indication illustrates the role of the pathologist in the diagnosis and management of breast cancer.

BREAST CANCER: In the United States, breast cancer is the most common female cancer, the second most common cancer death in women, and the main cause of death in women ages 45 to 55. One in six women in the United States will develop breast cancer during their lifetime. Fortunately, the rate of death from breast cancer has been declining in the US since 1990. This decline has been attributed both to treatment advances and to earlier detection through screening and increased public and individual awareness. Pathology and pathologists play an integral role in this initiative. Some of the processes both standard and evolving support those involved in treatment and management of this disease:

- Early detection through screening performed by periodic breast palpation, by mammographic imaging, and less commonly, by MRI.
- Characterization using MRI or PET scanning.
- Identification of mutations within either of two breast cancer susceptibility genes, named BRCA1 and BRCA2.
- Invasive techniques of fine needle aspiration and biopsy for tumor presence verification.
- Identification of cell type, disease extent and aggressiveness
- IHC and FISH have been widely used in diagnostic pathology and can be very useful to achieve a precise cancer diagnosis to ensure selection of the appropriate cancer therapeutic option. Estrogen receptor (ER), progesterone receptor (PR) and HER2/neu overexpression.

Breast cancer management entails a multidisciplinary approach involving specialists drawn from several different fields, including surgeons, radiation oncologists, medical oncologists, pathologists, nurses, and technicians. Each role is important, but it is the pathologist who establishes a definitive cancer diagnosis, and who provides clinical colleagues the information they require to identify or deliver optimized cancer care.

In summary, to make a cancer diagnosis requires specialized tissue processing and slides preparation, expert, highly trained pathologists to evaluate slides under the microscopy and apply precise diagnostic criteria to interpret the slides. Each step is controlled to ensure that all patients receive accurate diagnosis in a timely fashion. At ACM Global Central Laboratory, all cancer diagnoses are unanimously consented by the pathologists in our department.

Reference:

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