**Kazan (Volga region) Federal University**
**Department of Morphology and General Pathology**

**Lecture 2**

# Topic: Biopsy in clinical practice. Good Clinical Practice.

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# Plan:

1. The main stages of the histological processing of biopsy material.
2. The rules of clinical investigations

# Types of biopsies

**Biopsy (ancient Greek βίος — life + ὄψις — exterior) — a method of investigation, which is conducted by a lifetime collection of cells or tissue (biopsy) from the body for diagnostic or research purposes. A biopsy is required for the confirmation of the diagnosis if you suspect the presence of cancer.**

**By way of obtaining material**

**Obtaining material for histological examination by:**

- **Excisional Biopsy – obtaining pathological formation for the study entirely.**
- **Incisional Biopsy – obtaining the part of pathological formation or piece of organ of diffuse changed**
- **Punch-biopsy - using a biopsy forceps**
- **Trepanation Biopsy – obtaining a column of dense tissue using a hollow tube with a sharp edge - trepan. It is used for bone biopsy and solid tumors.**
- **Core-biopsy, core biopsy, cutting biopsy – obtatining a column of material from the soft tissue using a special trepan consisting of harpoon system and a hollow tube with a sharp edge.**
- **Shaving biopsy – obtaining material by removing the surface forming a thin layer of tissue used for biopsy of abnormal skin growths.**
- **Loop Biopsy – obtaining biopsy with loop using coagulator in cutting mode or radio-frequency surgical device. It is used in gynecology and endoscopic studies.**

**Obtaining material for cytological analysis:**

**- Print from pathological formation (erosion, ulcers) - the material is transferred to a glass slide by applying it to the ulcerated surface.**

**- Smear-printed from the pathological formation - the material is being scraped from the pathological formation using a spatula, scalpel, cytobrush then transferred onto a glass slide.**

**- Fine Needle Aspiration Biopsy (FNAB) - collection of material for analysis, usually by a puncture needle and syringe. It is used for biopsy of cysts and solid tumors.**

**- Aspiration Biopsy – FNAB version of liquid formations: cysts, sampling fluid from the pleural or peritoneal cavity.**

**By type of control accuracy:**

**- Classical Biopsy**

**- Sighting Biopsy**

**Endoscopic**

**Biopsy under ultrasound**

**A biopsy under X-ray**

# Rules of fixation


**Must not be used**


**81 ml - 85% formic acid, 171 мл - 33% hydrogenium peroxide. Mixture is placed for 2 hours into fridge occasionally shaking. Add distilled water up to 10 L obtaining 2,4% solution.**

# Rules of labeling

**«The Chocolate Girl » (french . *La Belle Chocolatière*, german *Das Schokoladenmädchen*) — the most famous painting of J. E. Liotard, XVIII c**

# Urgent biopsies

# Modern requirements to postmortem examination

**High-quality sample preparation**

**Standardization of all steps**

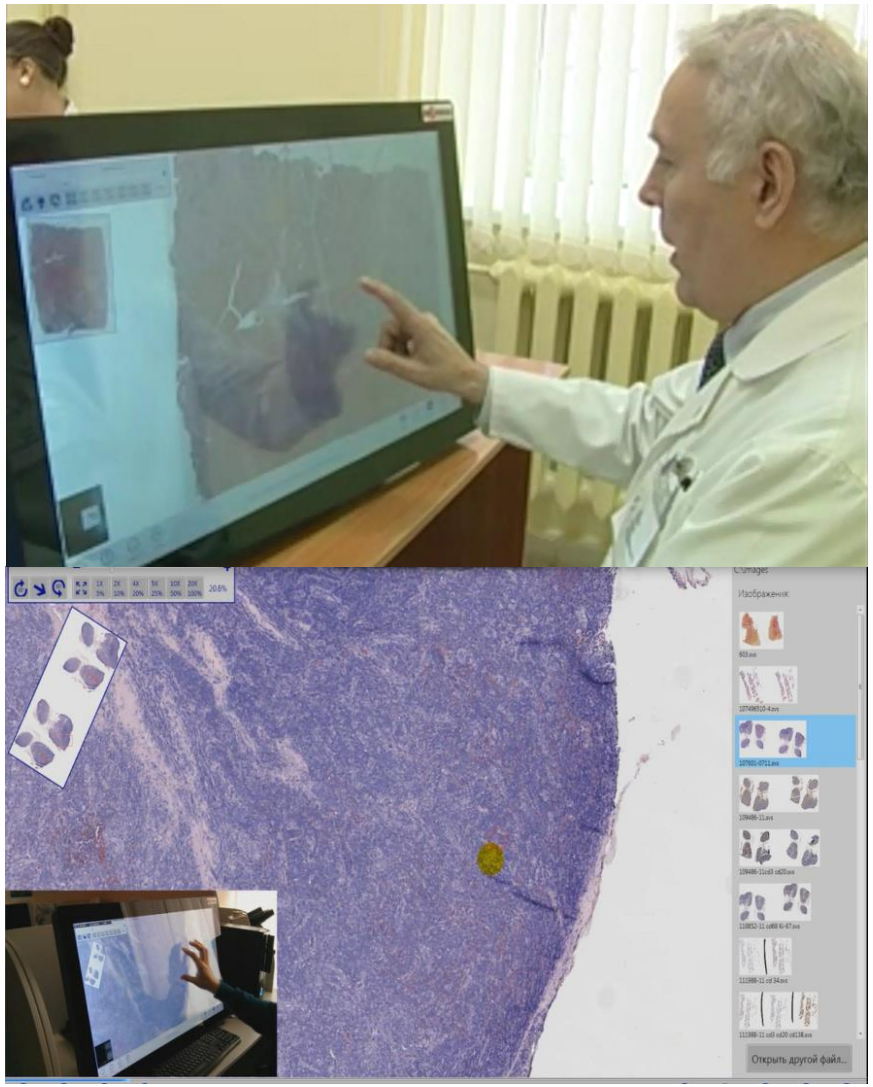
**«One day» result**

**Addition of molecular diagnostics methods**

# Modern ways to optimize the biopsy preparation

## Conveyor histoprocess

# Telepathology service - Histoscan.com



# GCP:

***Good Clinical Practice*** **— the international standard of ethics and quality of research, describing the rules of design, implementation, documentation and reporting on studies that involve human (clinical trials).**

**Compliance with this standard study declarate public compliance of:**

**-the rights of study participants**
**-rules to ensure their safety**
**-desire not to harm**
**-requirements for reliability studies**

# The main tasks and challenges of research:

1. It is necessary to obtain reliable data on the drug.

2. Do not expose people to unnecessary risk.

# Clinical trials phases

**Preclinical studies**

**Verification of the principle**

- **I phase  (A; B)**
- **II phase (A; B)**
- **III phase**
- **IV phase (postmarketing)**

- **A study of bioequivalence**

# 1 phase

**Study of:**

**- single dose tolerance**

**- pharmacokinetics parameters**

**- pharmacodynamic effects**

# 2 phase

**Aim:**

**- Demonstrate the clinical efficacy of the drug for a certain group of patients**

**- To evaluate short-term safety of the active ingredient**

**- Determining the level of a therapeutic dose**

**- Dosing**

# 3 phase

**Aims:**

- **identify short-term and long-term relationship safety / efficacy for formulations of the active ingredient**
- **determine its overall and relative therapeutic value**
- **specific characteristics of the products**
- **explore the profile and types of the most common adverse reactions**

# 4 phase

**It can be used:**

**- to improve the dosing regimens of the drug**

**- for different periods of treatment drug**

**- for interactions with food or other drugs**

**- for comparative analysis with other standard treatment, in other age groups, or other categories of patients**

**- to study the impact of long-term effects of the drug on survival (decrease or increase in mortality)**

**- to study the results of long-term use in patients of different groups**

# Conclusions: